Eigene Vorlage

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Sotrovimab (Xevudy)

GlaxoSmithKline GmbH & Co. KG

Separater Anhang 4-G
zu Modul 4A

Tabellen und Abbildungen

Stand: 10.05.2022

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Table 22.1
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29

Visit: Day 8

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	23 (4%)	2 (<1%)
Hospitalized > 24 hours	22 (4%)	2 (<1%)
Death	1 (<1%)	0
Alive and not hospitalized > 24 hours	503 (95%)	519 (98%)
Missing [1]	3 (<1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.33
95% C.I.		(0.15, 0.72)
p-value		0.005
Relative Risk [3]		0.34
95% C.I.		(0.16, 0.73)
p-value		0.006
Risk Difference (%) [4]		-3.21
95% C.I.		(-5.36, -1.06)
p-value		0.006

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.1
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29

Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	30 (6%)	3 (<1%)
Hospitalized > 24 hours	29 (5%)	3 (<1%)
Death	1 (<1%)	0
Alive and not hospitalized > 24 hours	495 (94%)	518 (98%)
Missing [1]	4 (<1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.28
95% C.I.		(0.14, 0.58)
p-value		<0.001
Relative Risk [3]		0.30
95% C.I.		(0.15, 0.59)
p-value		<0.001
Risk Difference (%) [4]		-4.53
95% C.I.		(-6.92, -2.14)
p-value		<0.001

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.1
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29

Visit: Day 22

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	30 (6%)	6 (1%)
Hospitalized > 24 hours	29 (5%)	6 (1%)
Death	2 (<1%)	0
Alive and not hospitalized > 24 hours	494 (93%)	515 (98%)
Missing [1]	5 (<1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.36
95% C.I.		(0.19, 0.69)
p-value		0.003
Relative Risk [3]		0.38
95% C.I.		(0.20, 0.70)
p-value		0.003
Risk Difference (%) [4]		-4.15
95% C.I.		(-6.65, -1.66)
p-value		0.002

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.1
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29

Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	30 (6%)	6 (1%)
Hospitalized > 24 hours	29 (5%)	6 (1%)
Death	2 (<1%)	0
Alive and not hospitalized > 24 hours	494 (93%)	515 (98%)
Missing [1]	5 (<1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.36
95% C.I.		(0.19, 0.69)
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Risk Difference (%) [4]		-4.15
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[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.2
Summary and Analysis of Proportion of Subjects with Hospitalization > 24 hours for Acute Management of any Illness through Day 29 (Primary Endpoint Component)

Visit: Day 8

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
Hospitalized > 24 hours	22 (4%)	2 (<1%)
Not hospitalized > 24 hours	503 (95%)	519 (98%)
Missing [1]	4 (<1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.34
95% C.I.		(0.16, 0.72)
p-value		0.006
Relative Risk [3]		0.35
95% C.I.		(0.16, 0.73)
p-value		0.006
Risk Difference (%) [4]		-3.21
95% C.I.		(-5.36, -1.06)
p-value		0.006

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.

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Table 22.2
Summary and Analysis of Proportion of Subjects with Hospitalization > 24 hours for Acute Management of any Illness through Day 29 (Primary Endpoint Component)

Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
Hospitalized > 24 hours	29 (5%)	3 (<1%)
Not hospitalized > 24 hours	495 (94%)	518 (98%)
Missing [1]	5 (<1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.28
95% C.I.		(0.14, 0.57)
p-value		<0.001
Relative Risk [3]		0.29
95% C.I.		(0.15, 0.59)
p-value		<0.001
Risk Difference (%) [4]		-4.53
95% C.I.		(-6.92, -2.14)
p-value		<0.001

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.

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Table 22.2
Summary and Analysis of Proportion of Subjects with Hospitalization > 24 hours for Acute Management of any Illness through Day 29 (Primary Endpoint Component)

Visit: Day 22

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
Hospitalized > 24 hours	29 (5%)	6 (1%)
Not hospitalized > 24 hours	494 (93%)	515 (98%)
Missing [1]	6 (1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.36
95% C.I.		(0.19, 0.68)
p-value		0.002
Relative Risk [3]		0.37
95% C.I.		(0.20, 0.70)
p-value		0.002
Risk Difference (%) [4]		-4.15
95% C.I.		(-6.65, -1.66)
p-value		0.002

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.

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Table 22.2
Summary and Analysis of Proportion of Subjects with Hospitalization > 24 hours for Acute Management of any Illness through Day 29 (Primary Endpoint Component)

Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
Hospitalized > 24 hours	29 (5%)	6 (1%)
Not hospitalized > 24 hours	494 (93%)	515 (98%)
Missing [1]	6 (1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.36
95% C.I.		(0.19, 0.68)
p-value		0.002
Relative Risk [3]		0.37
95% C.I.		(0.20, 0.70)
p-value		0.002
Risk Difference (%) [4]		-4.15
95% C.I.		(-6.65, -1.66)
p-value		0.002

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.

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Table 22.3
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29

Visit: Day 8

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	31 (6%)	9 (2%)
Hospitalized	23 (4%)	3 (<1%)
ER visit	8 (2%)	6 (1%)
Death	1 (<1%)	0
Alive and not hospitalized and no ER visit	495 (94%)	512 (97%)
Missing [1]	3 (<1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.45
95% C.I.		(0.25, 0.83)
p-value		0.011
Relative Risk [3]		0.47
95% C.I.		(0.26, 0.84)
p-value		0.011
Risk Difference (%) [4]		-3.40
95% C.I.		(-5.95, -0.85)
p-value		0.014

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.3
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29

Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	39 (7%)	10 (2%)
Hospitalized	29 (5%)	4 (<1%)
ER visit	10 (2%)	6 (1%)
Death	1 (<1%)	0
Alive and not hospitalized and no ER visit	486 (92%)	511 (97%)
Missing [1]	4 (<1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.37
95% C.I.		(0.21, 0.67)
p-value		<0.001
Relative Risk [3]		0.40
95% C.I.		(0.23, 0.68)
p-value		<0.001
Risk Difference (%) [4]		-4.91
95% C.I.		(-7.68, -2.14)
p-value		<0.001

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.3
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29

Visit: Day 22

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	39 (7%)	13 (2%)
Hospitalized	29 (5%)	7 (1%)
ER visit	10 (2%)	6 (1%)
Death	2 (<1%)	0
Alive and not hospitalized and no ER visit	485 (92%)	508 (96%)
Missing [1]	5 (<1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.43
95% C.I.		(0.25, 0.75)
p-value		0.003
Relative Risk [3]		0.46
95% C.I.		(0.27, 0.76)
p-value		0.003
Risk Difference (%) [4]		-4.53
95% C.I.		(-7.39, -1.67)
p-value		0.003

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.3
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29

Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	39 (7%)	13 (2%)
Hospitalized	29 (5%)	7 (1%)
ER visit	10 (2%)	6 (1%)
Death	2 (<1%)	0
Alive and not hospitalized and no ER visit	485 (92%)	508 (96%)
Missing [1]	5 (<1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.43
95% C.I.		(0.25, 0.75)
p-value		0.003
Relative Risk [3]		0.46
95% C.I.		(0.27, 0.76)
p-value		0.003
Risk Difference (%) [4]		-4.53
95% C.I.		(-7.39, -1.67)
p-value		0.003

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.4
Summary and Analysis of Proportion of Subjects with Hospitalization for Acute Management of any Illness through Day 29 (Secondary Endpoint Component)

Visit: Day 8

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
Hospitalized	23 (4%)	3 (<1%)
Not hospitalized	502 (95%)	518 (98%)
Missing [1]	4 (<1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.36
95% C.I.		(0.17, 0.75)
p-value		0.007
Relative Risk [3]		0.37
95% C.I.		(0.18, 0.76)
p-value		0.007
Risk Difference (%) [4]		-3.21
95% C.I.		(-5.42, -1.00)
p-value		0.007

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.

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Table 22.4
Summary and Analysis of Proportion of Subjects with Hospitalization for Acute Management of any Illness through Day 29 (Secondary Endpoint Component)

Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
Hospitalized	29 (5%)	4 (<1%)
Not hospitalized	495 (94%)	517 (98%)
Missing [1]	5 (<1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.31
95% C.I.		(0.16, 0.62)
p-value		<0.001
Relative Risk [3]		0.32
95% C.I.		(0.17, 0.63)
p-value		<0.001
Risk Difference (%) [4]		-4.34
95% C.I.		(-6.76, -1.92)
p-value		<0.001

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.

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Table 22.4
Summary and Analysis of Proportion of Subjects with Hospitalization for Acute Management of any Illness through Day 29 (Secondary Endpoint Component)

Visit: Day 22

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
Hospitalized	29 (5%)	7 (1%)
Not hospitalized	494 (93%)	514 (97%)
Missing [1]	6 (1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.38
95% C.I.		(0.20, 0.72)
p-value		0.004
Relative Risk [3]		0.40
95% C.I.		(0.22, 0.74)
p-value		0.004
Risk Difference (%) [4]		-3.96
95% C.I.		(-6.49, -1.44)
p-value		0.004

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.

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Table 22.4
Summary and Analysis of Proportion of Subjects with Hospitalization for Acute Management of any Illness through Day 29 (Secondary Endpoint Component)

Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
Hospitalized	29 (5%)	7 (1%)
Not hospitalized	494 (93%)	514 (97%)
Missing [1]	6 (1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.38
95% C.I.		(0.20, 0.72)
p-value		0.004
Relative Risk [3]		0.40
95% C.I.		(0.22, 0.74)
p-value		0.004
Risk Difference (%) [4]		-3.96
95% C.I.		(-6.49, -1.44)
p-value		0.004

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.

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Table 22.5
Summary and Analysis of Proportion of Subjects with Emergency Room Visit through Day 29 (Secondary Endpoint Component)

Visit: Day 8

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
ER visit	8 (2%)	6 (1%)
No ER visit	517 (98%)	515 (98%)
Missing [1]	4 (<1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		1.09
95% C.I.		(0.49, 2.41)
p-value		0.836
Relative Risk [3]		1.09
95% C.I.		(0.50, 2.36)
p-value		0.836
Risk Difference (%) [4]		0.19
95% C.I.		(-1.64, 2.03)
p-value		0.844

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as ER visits.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.

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Table 22.5
Summary and Analysis of Proportion of Subjects with Emergency Room Visit through Day 29 (Secondary Endpoint Component)

Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
ER visit	10 (2%)	6 (1%)
No ER visit	514 (97%)	515 (98%)
Missing [1]	5 (<1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.86
95% C.I.		(0.41, 1.84)
p-value		0.706
Relative Risk [3]		0.87
95% C.I.		(0.42, 1.81)
p-value		0.706
Risk Difference (%) [4]		-0.37
95% C.I.		(-2.31, 1.56)
p-value		0.849

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as ER visits.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.

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Table 22.5
Summary and Analysis of Proportion of Subjects with Emergency Room Visit through Day 29 (Secondary Endpoint Component)

Visit: Day 22

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
ER visit	10 (2%)	6 (1%)
No ER visit	509 (96%)	514 (97%)
Missing [1]	10 (2%)	8 (2%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.69
95% C.I.		(0.35, 1.39)
p-value		0.301
Relative Risk [3]		0.70
95% C.I.		(0.36, 1.37)
p-value		0.301
Risk Difference (%) [4]		-1.13
95% C.I.		(-3.26, 1.00)
p-value		0.384

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as ER visits.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.

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Table 22.5
Summary and Analysis of Proportion of Subjects with Emergency Room Visit through Day 29 (Secondary Endpoint Component)

Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
ER visit	10 (2%)	6 (1%)
No ER visit	508 (96%)	514 (97%)
Missing [1]	11 (2%)	8 (2%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.66
95% C.I.		(0.33, 1.31)
p-value		0.235
Relative Risk [3]		0.67
95% C.I.		(0.34, 1.30)
p-value		0.235
Risk Difference (%) [4]		-1.32
95% C.I.		(-3.47, 0.84)
p-value		0.303

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as ER visits.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.

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Table 22.6
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29

Visit: Day 8

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
No Progression [1]	506 (96%)	515 (98%)
Any Progression	20 (4%)	6 (1%)
Category 2: Low flow nasal cannulae/face mask	7 (1%)	6 (1%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	11 (2%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	1 (<1%)	0
Death	1 (<1%)	0
Missing [2]	3 (<1%)	7 (1%)

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.6
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29

Visit: Day 8

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.55
95% C.I.		(0.28, 1.11)
p-value		0.096
Relative Risk [4]		0.57
95% C.I.		(0.29, 1.10)
p-value		0.095
Risk Difference (%) [5]		-1.89
95% C.I.		(-4.07, 0.30)
p-value		0.126

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.6
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29

Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
No Progression [1]	497 (94%)	515 (98%)
Any Progression	28 (5%)	6 (1%)
Category 2: Low flow nasal cannulae/face mask	12 (2%)	6 (1%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	11 (2%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	4 (<1%)	0
Death	1 (<1%)	0
Missing [2]	4 (<1%)	7 (1%)

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.6
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29

Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.39
95% C.I.		(0.20, 0.76)
p-value		0.006
Relative Risk [4]		0.41
95% C.I.		(0.22, 0.76)
p-value		0.006
Risk Difference (%) [5]		-3.59
95% C.I.		(-6.01, -1.16)
p-value		0.006

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.6
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29

Visit: Day 22

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
No Progression [1]	495 (94%)	514 (97%)
Any Progression	28 (5%)	7 (1%)
Category 2: Low flow nasal cannulae/face mask	12 (2%)	7 (1%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	10 (2%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	4 (<1%)	0
Death	2 (<1%)	0
Missing [2]	6 (1%)	7 (1%)

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.6
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29

Visit: Day 22

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.40
95% C.I.		(0.21, 0.75)
p-value		0.005
Relative Risk [4]		0.41
95% C.I.		(0.23, 0.76)
p-value		0.005
Risk Difference (%) [5]		-3.78
95% C.I.		(-6.27, -1.28)
p-value		0.005

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.6
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29

Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Progression Status, n (%)		
No Progression [1]	495 (94%)	514 (97%)
Any Progression	28 (5%)	7 (1%)
Category 2: Low flow nasal cannulae/face mask	12 (2%)	7 (1%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	10 (2%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	4 (<1%)	0
Death	2 (<1%)	0
Missing [2]	6 (1%)	7 (1%)

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.6
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29

Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.40
95% C.I.		(0.21, 0.75)
p-value		0.005
Relative Risk [4]		0.41
95% C.I.		(0.23, 0.76)
p-value		0.005
Risk Difference (%) [5]		-3.78
95% C.I.		(-6.27, -1.28)
p-value		0.005

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point. Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 2.35
Summary of Duration on Ventilator

Time point: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Alive and never on ventilation [1]	514 (97%)	521 (99%)
On ventilation [2]	4 (<1%)	0
1 period	4 (<1%)	0
2 periods	0	0
>2 periods	0	0
Incomplete follow-up due to study withdrawal	9 (2%)	7 (1%)
On ventilation prior to study withdrawal	0	0
Withdrawn and never on ventilation	9 (2%)	7 (1%)
Incomplete follow-up due to death [3]	2 (<1%)	0
On ventilation prior to death	0	0
Deceased and never on ventilation	2 (<1%)	0
Ventilator use [3]		
0 days	523 (99%)	528 (100%)
1 - <=8 days	0	0
9 - <=15 days	2 (<1%)	0
16 - <=22 days	3 (<1%)	0
23 - <=29 days	1 (<1%)	0

[1] Alive and never on ventilation based on complete follow-up data up to the time point.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to the time point of interest were considered to be on ventilation from date of death until the time point of interest.
Note: Ventilation use is assessed from the date of randomization for the number of days specified in the

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Table 2.35
Summary of Duration on Ventilator

Time point: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Duration (days) - All subjects [3]		
Mean	0.2	0.0
SD	1.84	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	25	0
Duration (days) - Subjects with event/death [3]		
n	6	0
Mean	16.3	
SD	6.35	
Median	16.0	
IQR	10.0 - 22.0	
Min.	9	
Max.	25	

[1] Alive and never on ventilation based on complete follow-up data up to the time point.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to the time point of interest were considered to be on ventilation from date of death until the time point of interest.
Note: Ventilation use is assessed from the date of randomization for the number of days specified in the time point.

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Table 2.36
Summary of Duration in Intensive Care Unit

Time point: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Alive and never entered ICU [1]	510 (96%)	521 (99%)
Entered ICU [2]	9 (2%)	0
1 stay	9 (2%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	9 (2%)	7 (1%)
Entered ICU prior to study withdrawal	0	0
Withdrawn and never entered ICU	9 (2%)	7 (1%)
Incomplete follow-up due to death [3]	2 (<1%)	0
Entered ICU prior to death	1 (<1%)	0
Deceased and never entered ICU	1 (<1%)	0
ICU Stay [3]		
0 days	519 (98%)	528 (100%)
1 - <=8 days	2 (<1%)	0
9 - <=15 days	3 (<1%)	0
16 - <=22 days	2 (<1%)	0
23 - <=29 days	3 (<1%)	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to the time point.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to the time point of interest were considered to be in the intensive care unit from date of death until the time point of interest.
Note: Time spent in the intensive care unit is assessed from the date of randomization for the number of days specified in the time point.

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Table 2.36
Summary of Duration in Intensive Care Unit

Time point: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Duration (days) - All subjects [3]		
Mean	0.3	0.0
SD	2.36	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	25	0
Duration (days) - Subjects with event/death [3]		
n	10	0
Mean	15.8	
SD	7.30	
Median	14.5	
IQR	9.0 - 24.0	
Min.	6	
Max.	25	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to the time point.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to the time point of interest were considered to be in the intensive care unit from date of death until the time point of interest.
Note: Time spent in the intensive care unit is assessed from the date of randomization for the number of days specified in the time point.

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Table 2.37
Summary of Duration in Hospital

Time point: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Alive and never entered hospital [1]	494 (93%)	515 (98%)
Entered hospital [2]	29 (5%)	7 (1%)
1 stay	29 (5%)	7 (1%)
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	9 (2%)	7 (1%)
Entered hospital prior to study withdrawal	4 (<1%)	1 (<1%)
Withdrawn and never entered hospital	5 (<1%)	6 (1%)
Incomplete follow-up due to death [3]	2 (<1%)	0
Entered hospital prior to death	1 (<1%)	0
Deceased and never entered hospital	1 (<1%)	0
Hospital Stay [3]		
0 days	499 (94%)	521 (99%)
>0 - <=24 hours	0	1 (<1%)
>1 - <=8 days	19 (4%)	3 (<1%)
9 - <=15 days	3 (<1%)	2 (<1%)
16 - <=22 days	4 (<1%)	1 (<1%)
23 - <=29 days	4 (<1%)	0

[1] Alive and never entered hospital based on complete follow-up data up to the time point.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to the time point of interest were considered to be in hospital from date of death until the time point of interest.
Note: Time spent in hospital is assessed from the date of randomization for the number of days specified in the time point.

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Table 2.37
Summary of Duration in Hospital

Time point: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Duration (days) - All subjects [3]		
Mean	0.6	0.1
SD	2.90	1.05
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	25	16
Duration (days) - Subjects with event/death [3]		
n	30	7
Mean	10.0	7.7
SD	7.49	5.25
Median	6.5	7.0
IQR	5.0 - 16.0	3.0 - 11.0
Min.	2	1
Max.	25	16

[1] Alive and never entered hospital based on complete follow-up data up to the time point.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to the time point of interest were considered to be in hospital from date of death until the time point of interest.
Note: Time spent in hospital is assessed from the date of randomization for the number of days specified in the time point.

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Table 22.7
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29

Visit: Day 8

	Placebo (N=529)	VIR-7831 500mg (N=528)
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	3 (<1%)	1 (<1%)
Hospitalized due to non-respiratory complications	2 (<1%)	1 (<1%)
Death	1 (<1%)	0
Alive and not hospitalized due to non-respiratory complications	523 (99%)	520 (98%)
Missing [1]	3 (<1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		1.34
95% C.I.		(0.46, 3.89)
p-value		0.590
Relative Risk [3]		1.34
95% C.I.		(0.47, 3.82)
p-value		0.590
Risk Difference (%) [4]		0.38
95% C.I.		(-1.00, 1.76)
p-value		0.605

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test

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Table 22.7
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29

Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	4 (<1%)	2 (<1%)
Hospitalized due to non-respiratory complications	3 (<1%)	2 (<1%)
Death	1 (<1%)	0
Alive and not hospitalized due to non-respiratory complications	521 (98%)	519 (98%)
Missing [1]	4 (<1%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		1.13
95% C.I.		(0.43, 2.95)
p-value		0.804
Relative Risk [3]		1.13
95% C.I.		(0.44, 2.90)
p-value		0.804
Risk Difference (%) [4]		0.19
95% C.I.		(-1.32, 1.71)
p-value		0.813

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test

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Table 22.7
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29

Visit: Day 22

	Placebo (N=529)	VIR-7831 500mg (N=528)
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	5 (<1%)	4 (<1%)
Hospitalized due to non-respiratory complications	3 (<1%)	4 (<1%)
Death	2 (<1%)	0
Alive and not hospitalized due to non-respiratory complications	516 (98%)	516 (98%)
Missing [1]	8 (2%)	8 (2%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.92
95% C.I.		(0.42, 2.04)
p-value		0.844
Relative Risk [3]		0.92
95% C.I.		(0.43, 2.01)
p-value		0.844
Risk Difference (%) [4]		-0.18
95% C.I.		(-2.02, 1.65)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test

Table 22.7
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29

Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	6 (1%)	4 (<1%)
Hospitalized due to non-respiratory complications	4 (<1%)	4 (<1%)
Death	2 (<1%)	0
Alive and not hospitalized due to non-respiratory complications	514 (97%)	516 (98%)
Missing [1]	9 (2%)	8 (2%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.80
95% C.I.		(0.37, 1.72)
p-value		0.563
Relative Risk [3]		0.80
95% C.I.		(0.38, 1.70)
p-value		0.563
Risk Difference (%) [4]		-0.56
95% C.I.		(-2.46, 1.34)
p-value		0.698

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 2.103
Summary of Duration on Ventilator through Day 90

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Alive and never on ventilation [1]	510 (96%)	519 (98%)
On ventilation [2]	4 (<1%)	0
1 period	4 (<1%)	0
2 periods	0	0
>2 periods	0	0
Incomplete follow-up due to study withdrawal	13 (2%)	9 (2%)
On ventilation prior to study withdrawal	0	0
Withdrawn and never on ventilation	13 (2%)	9 (2%)
Incomplete follow-up due to death [3]	4 (<1%)	0
On ventilation prior to death	2 (<1%)	0
Deceased and never on ventilation	2 (<1%)	0
Ventilator use [3]		
0 days	523 (99%)	528 (100%)
1 - <=8 days	0	0
9 - <=15 days	1 (<1%)	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	1 (<1%)	0
60 - <=90 days	4 (<1%)	0

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Table 2.103
Summary of Duration on Ventilator through Day 90

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.7	0.0
SD	7.07	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	0
Duration (days) - Subjects with event/death [3]		
n	6	0
Mean	61.3	
SD	28.67	
Median	74.0	
IQR	48.0 - 77.0	
Min.	9	
Max.	86	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 2.105
Summary of Duration in Intensive Care Unit through Day 90

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Alive and never entered ICU [1]	507 (96%)	519 (98%)
Entered ICU [2]	9 (2%)	0
1 stay	9 (2%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	13 (2%)	9 (2%)
Entered ICU prior to study withdrawal	1 (<1%)	0
Withdrawn and never entered ICU	12 (2%)	9 (2%)
Incomplete follow-up due to death [3]	4 (<1%)	0
Entered ICU prior to death	3 (<1%)	0
Deceased and never entered ICU	1 (<1%)	0
ICU Stay [3]		
0 days	519 (98%)	528 (100%)
1 - <=8 days	2 (<1%)	0
9 - <=15 days	2 (<1%)	0
16 - <=22 days	0	0
23 - <=29 days	1 (<1%)	0
30 - <=59 days	1 (<1%)	0
60 - <=90 days	4 (<1%)	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 2.105
Summary of Duration in Intensive Care Unit through Day 90

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.8	0.0
SD	7.18	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	0
Duration (days) - Subjects with event/death [3]		
n	10	0
Mean	41.4	
SD	33.95	
Median	30.5	
IQR	9.0 - 77.0	
Min.	6	
Max.	86	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 2.106
Summary of Duration in Hospital through Day 90

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Alive and never entered hospital [1]	489 (92%)	509 (96%)
Entered hospital [2]	31 (6%)	11 (2%)
1 stay	30 (6%)	10 (2%)
2 stays	1 (<1%)	1 (<1%)
>2 stays	0	0
Incomplete follow-up due to study withdrawal	13 (2%)	9 (2%)
Entered hospital prior to study withdrawal	5 (<1%)	1 (<1%)
Withdrawn and never entered hospital	8 (2%)	8 (2%)
Incomplete follow-up due to death [3]	4 (<1%)	0
Entered hospital prior to death	3 (<1%)	0
Deceased and never entered hospital	1 (<1%)	0
Hospital Stay [3]		
0 days	497 (94%)	517 (98%)
>0 - <=24 hours	0	2 (<1%)
>1 - <=8 days	21 (4%)	5 (<1%)
9 - <=15 days	3 (<1%)	2 (<1%)
16 - <=22 days	2 (<1%)	1 (<1%)
23 - <=29 days	0	0
30 - <=59 days	2 (<1%)	1 (<1%)
60 - <=90 days	4 (<1%)	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 2.106
Summary of Duration in Hospital through Day 90

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	1.1	0.2
SD	7.85	2.49
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	51
Duration (days) - Subjects with event/death [3]		
n	32	11
Mean	18.5	10.6
SD	26.81	14.33
Median	6.0	5.0
IQR	4.0 - 13.5	3.0 - 14.0
Min.	2	1
Max.	86	51

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Virology Data as of 27APR2021

Table 2.18
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
Baseline	Viral Load (log10 copies/mL)	n	385	369
		Mean	6.645	6.535
		SD	1.6632	1.6331
		Median	6.824	6.609
		Min.	3.367	3.373
		Max.	9.941	9.985
Day 5	Viral Load (log10 copies/mL)	n	331	323
		Mean	5.188	4.685
		SD	1.7578	1.4517
		Median	5.059	4.384
		Min.	2.873	2.873
		Max.	9.614	8.830
	Change from Baseline (log10 copies/mL)	n	331	323
		Mean	-1.488	-1.925
		SD	1.4971	1.3113
		Median	-1.542	-1.894
		Min.	-5.210	-5.251
		Max.	3.455	3.306

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the

Protocol: 214367
Population: Virology Data as of 27APR2021

Table 2.18
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
Day 8	Viral Load (log10 copies/mL)	n	323	316
		Mean	4.276	3.989
		SD	1.3646	1.1913
		Median	3.939	3.554
		Min.	2.873	2.873
		Max.	8.416	8.231
	Change from Baseline (log10 copies/mL)	n	323	316
		Mean	-2.444	-2.625
		SD	1.5076	1.4609
		Median	-2.451	-2.682
		Min.	-5.875	-5.981
		Max.	4.615	2.328
Day 11	Viral Load (log10 copies/mL)	n	324	322
		Mean	3.842	3.697
		SD	1.1502	1.0421
		Median	3.270	3.270
		Min.	2.873	2.873
		Max.	8.470	8.398
	Change from Baseline (log10 copies/mL)	n	324	322
		Mean	-2.811	-2.835
		SD	1.5828	1.6255
		Median	-2.890	-2.919
		Min.	-6.265	-6.487
		Max.	4.647	2.561

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

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Population: Virology Data as of 27APR2021

Table 2.18
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
Day 15	Viral Load (log10 copies/mL)	n	302	293
		Mean	3.426	3.362
		SD	0.8361	0.6750
		Median	3.270	3.270
		Min.	2.873	2.873
		Max.	7.450	6.450
	Change from Baseline (log10 copies/mL)	n	302	293
		Mean	-3.151	-3.205
		SD	1.5977	1.4868
		Median	-3.072	-3.326
		Min.	-7.068	-6.480
		Max.	3.108	0.359
Day 22	Viral Load (log10 copies/mL)	n	301	306
		Mean	3.169	3.059
		SD	0.5591	0.3678
		Median	2.873	2.873
		Min.	2.873	2.873
		Max.	6.625	6.471
	Change from Baseline (log10 copies/mL)	n	301	306
		Mean	-3.412	-3.458
		SD	1.5883	1.5667
		Median	-3.416	-3.495
		Min.	-7.068	-6.877
		Max.	1.291	0.393

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

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Population: Virology Data as of 27APR2021

Table 2.18
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
Day 29	Viral Load (log10 copies/mL)	n	323	312
		Mean	3.038	3.017
		SD	0.3927	0.3861
		Median	2.873	2.873
		Min.	2.873	2.873
		Max.	5.825	6.178
	Change from Baseline (log10 copies/mL)	n	323	312
		Mean	-3.536	-3.460
		SD	1.6241	1.6160
		Median	-3.726	-3.504
		Min.	-7.068	-7.112
		Max.	0.323	-0.355

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

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Protocol: 214367
Population: Virology Data as of 27APR2021

Table 22.8
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit: Day 5

	Placebo (N=385)	VIR-7831 500mg (N=369)
n [1]	373	364
n [2]	331	323
LS Mean (SE)	5.133 (0.0683)	4.659 (0.0690)
95% C.I.	(4.999, 5.267)	(4.524, 4.795)
LS Mean Change from Baseline (SE)	-1.441 (0.0683)	-1.915 (0.0690)
95% C.I.	(-1.575, -1.307)	(-2.050, -1.779)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.474 (0.0970)
95% C.I.		(-0.664, -0.283)
p-value		<0.001
Corrected Hedge’s g (SE) [3]		-0.381 (0.0789)
95% C.I.		(-0.536, -0.227)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline, visit, baseline by visit and treatment by visit interactions.
Note: Only change from baseline at Day 8 is part of the secondary endpoint testing hierarchy.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Protocol: 214367
Population: Virology Data as of 27APR2021

Table 22.8
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit: Day 8

	Placebo (N=385)	VIR-7831 500mg (N=369)
n [1]	373	364
n [2]	323	316
LS Mean (SE)	4.221 (0.0592)	3.966 (0.0597)
95% C.I.	(4.105, 4.337)	(3.849, 4.083)
LS Mean Change from Baseline (SE)	-2.353 (0.0592)	-2.608 (0.0597)
95% C.I.	(-2.469, -2.237)	(-2.725, -2.491)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.255 (0.0841)
95% C.I.		(-0.420, -0.090)
p-value		0.003
Corrected Hedge’s g (SE) [3]		-0.240 (0.0794)
95% C.I.		(-0.395, -0.084)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline, visit, baseline by visit and treatment by visit interactions.
Note: Only change from baseline at Day 8 is part of the secondary endpoint testing hierarchy.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

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Population: Virology Data as of 27APR2021

Table 22.8
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit: Day 11

	Placebo (N=385)	VIR-7831 500mg (N=369)
n [1]	373	364
n [2]	324	322
LS Mean (SE)	3.822 (0.0544)	3.691 (0.0546)
95% C.I.	(3.715, 3.929)	(3.584, 3.798)
LS Mean Change from Baseline (SE)	-2.752 (0.0544)	-2.883 (0.0546)
95% C.I.	(-2.859, -2.645)	(-2.991, -2.776)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.131 (0.0770)
95% C.I.		(-0.283, 0.020)
p-value		0.089
Corrected Hedge’s g (SE) [3]		-0.134 (0.0788)
95% C.I.		(-0.288, 0.020)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline, visit, baseline by visit and treatment by visit interactions.
Note: Only change from baseline at Day 8 is part of the secondary endpoint testing hierarchy.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

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Population: Virology Data as of 27APR2021

Table 22.8
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit: Day 15

	Placebo (N=385)	VIR-7831 500mg (N=369)
n [1]	373	364
n [2]	302	293
LS Mean (SE)	3.407 (0.0384)	3.343 (0.0389)
95% C.I.	(3.331, 3.482)	(3.266, 3.419)
LS Mean Change from Baseline (SE)	-3.167 (0.0384)	-3.232 (0.0389)
95% C.I.	(-3.243, -3.092)	(-3.308, -3.155)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.064 (0.0547)
95% C.I.		(-0.172, 0.043)
p-value		0.241
Corrected Hedge’s g (SE) [3]		-0.096 (0.0820)
95% C.I.		(-0.257, 0.065)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline, visit, baseline by visit and treatment by visit interactions.
Note: Only change from baseline at Day 8 is part of the secondary endpoint testing hierarchy.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

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Population: Virology Data as of 27APR2021

Table 22.8
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit: Day 22

	Placebo (N=385)	VIR-7831 500mg (N=369)
n [1]	373	364
n [2]	301	306
LS Mean (SE)	3.167 (0.0243)	3.068 (0.0242)
95% C.I.	(3.119, 3.215)	(3.020, 3.115)
LS Mean Change from Baseline (SE)	-3.407 (0.0243)	-3.506 (0.0242)
95% C.I.	(-3.455, -3.359)	(-3.554, -3.459)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.099 (0.0343)
95% C.I.		(-0.167, -0.032)
p-value		0.004
Corrected Hedge’s g (SE) [3]		-0.235 (0.0815)
95% C.I.		(-0.395, -0.075)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline, visit, baseline by visit and treatment by visit interactions.
Note: Only change from baseline at Day 8 is part of the secondary endpoint testing hierarchy.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Protocol: 214367
Population: Virology Data as of 27APR2021

Table 22.8
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit: Day 29

	Placebo (N=385)	VIR-7831 500mg (N=369)
n [1]	373	364
n [2]	323	312
LS Mean (SE)	3.046 (0.0204)	3.027 (0.0207)
95% C.I.	(3.005, 3.086)	(2.986, 3.067)
LS Mean Change from Baseline (SE)	-3.529 (0.0204)	-3.547 (0.0207)
95% C.I.	(-3.569, -3.489)	(-3.588, -3.507)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.019 (0.0290)
95% C.I.		(-0.076, 0.038)
p-value		0.520
Corrected Hedge’s g (SE) [3]		-0.051 (0.0794)
95% C.I.		(-0.207, 0.105)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline, visit, baseline by visit and treatment by visit interactions.
Note: Only change from baseline at Day 8 is part of the secondary endpoint testing hierarchy.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 2.115
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Viral Load (log10 copies/mL)	n	483	475
		Mean	2.682	2.688
		SD	0.0467	0.0775
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	3.333	3.899
Day 8	Viral Load (log10 copies/mL)	n	55	62
		Mean	2.692	2.676
		SD	0.0690	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.977	2.676
	Change from Baseline (log10 copies/mL)	n	20	22
		Mean	-0.048	-0.151
		SD	0.1175	0.1541
		Median	0.000	-0.151
		Min.	-0.356	-0.301
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Table 2.115
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Day 15	Viral Load (log10 copies/mL)	n	32	32
		Mean	2.676	2.676
		SD	0.0000	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.676	2.676
	Change from Baseline (log10 copies/mL)	n	10	14
		Mean	-0.186	-0.215
		SD	0.2231	0.1411
		Median	-0.151	-0.301
		Min.	-0.657	-0.301
		Max.	0.000	0.000
Day 29	Viral Load (log10 copies/mL)	n	65	70
		Mean	2.676	2.676
		SD	0.0000	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.676	2.676
	Change from Baseline (log10 copies/mL)	n	43	52
		Mean	-0.050	-0.069
		SD	0.1360	0.1281
		Median	0.000	0.000
		Min.	-0.657	-0.301
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.1
Summary of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Total Score

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 7	n	399	412
	Mean	-1.98	-3.04
	SD	2.736	2.895
	Median	-1.47	-2.64
	Min.	-13.6	-12.3
	Max.	6.0	4.1
AUC to Day 14	n	373	385
	Mean	-7.08	-9.36
	SD	6.297	7.255
	Median	-5.86	-8.27
	Min.	-31.1	-34.1
	Max.	6.6	8.2
AUC to Day 21	n	345	379
	Mean	-13.55	-16.22
	SD	10.266	11.703
	Median	-11.67	-14.33
	Min.	-53.1	-57.8
	Max.	5.9	15.8

F approach.
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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.1
Summary of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Nose

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 7	n	401	412
	Mean	-2.40	-2.86
	SD	3.902	3.967
	Median	-2.13	-2.44
	Min.	-18.1	-15.8
	Max.	8.3	7.4
AUC to Day 14	n	375	385
	Mean	-8.38	-9.21
	SD	8.874	9.643
	Median	-7.38	-7.88
	Min.	-44.4	-40.6
	Max.	13.4	15.6
AUC to Day 21	n	347	379
	Mean	-15.67	-16.09
	SD	14.505	15.186
	Median	-13.63	-14.00
	Min.	-60.4	-59.0
	Max.	13.4	25.0

F approach.
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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.1
Summary of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Throat

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 7	n	401	412
	Mean	-2.19	-3.00
	SD	4.108	4.313
	Median	-1.50	-1.83
	Min.	-22.0	-18.3
	Max.	15.5	11.0
AUC to Day 14	n	375	385
	Mean	-7.23	-8.73
	SD	9.644	10.317
	Median	-5.17	-6.33
	Min.	-49.3	-42.0
	Max.	12.5	25.0
AUC to Day 21	n	347	379
	Mean	-13.25	-14.92
	SD	15.479	16.912
	Median	-10.50	-11.00
	Min.	-65.0	-70.0
	Max.	20.2	28.0

F approach.
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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.1
Summary of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Eyes

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 7	n	401	412
	Mean	-1.68	-2.19
	SD	4.019	3.933
	Median	-0.67	-0.83
	Min.	-18.0	-17.2
	Max.	10.7	11.0
AUC to Day 14	n	375	385
	Mean	-5.72	-6.62
	SD	9.306	9.679
	Median	-3.83	-3.83
	Min.	-41.3	-37.8
	Max.	22.2	25.0
AUC to Day 21	n	347	379
	Mean	-10.56	-11.33
	SD	14.927	15.477
	Median	-7.50	-6.17
	Min.	-64.7	-63.3
	Max.	28.0	34.5

F approach.

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.1
Summary of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Chest/Respiratory

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 7	n	401	412
	Mean	-1.24	-2.66
	SD	3.074	3.300
	Median	-0.93	-2.14
	Min.	-13.5	-12.0
	Max.	7.4	7.3
AUC to Day 14	n	375	385
	Mean	-5.30	-8.56
	SD	7.219	8.229
	Median	-4.21	-7.29
	Min.	-27.6	-34.3
	Max.	18.2	12.9
AUC to Day 21	n	347	379
	Mean	-10.90	-15.41
	SD	11.846	13.144
	Median	-9.07	-12.93
	Min.	-49.6	-58.3
	Max.	25.0	18.4

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.1
Summary of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Gastrointestinal

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 7	n	399	412
	Mean	-1.40	-2.21
	SD	3.132	3.561
	Median	-0.50	-1.13
	Min.	-17.5	-15.8
	Max.	6.8	6.0
AUC to Day 14	n	373	385
	Mean	-4.70	-6.72
	SD	7.333	8.614
	Median	-2.63	-3.88
	Min.	-42.0	-43.8
	Max.	15.4	8.4
AUC to Day 21	n	345	379
	Mean	-9.02	-11.17
	SD	11.981	13.788
	Median	-4.88	-7.25
	Min.	-66.5	-71.8
	Max.	18.8	12.3

F approach.
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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.1
Summary of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Body/Systemic

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 7	n	400	412
	Mean	-2.53	-3.90
	SD	3.649	3.756
	Median	-2.00	-3.57
	Min.	-15.6	-15.4
	Max.	7.5	5.3
AUC to Day 14	n	374	385
	Mean	-8.93	-11.80
	SD	8.342	9.214
	Median	-7.80	-11.27
	Min.	-36.3	-37.6
	Max.	9.1	10.6
AUC to Day 21	n	346	379
	Mean	-17.01	-20.32
	SD	13.282	14.795
	Median	-15.80	-19.45
	Min.	-58.9	-63.7
	Max.	9.3	14.5

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.1
Summary of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Sense

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 7	n	399	412
	Mean	-0.09	-0.57
	SD	2.005	2.286
	Median	0.00	0.00
	Min.	-5.5	-5.5
	Max.	5.5	5.5
AUC to Day 14	n	373	385
	Mean	-1.13	-2.45
	SD	4.987	5.763
	Median	0.00	0.00
	Min.	-12.5	-12.5
	Max.	12.5	12.5
AUC to Day 21	n	345	379
	Mean	-3.30	-4.86
	SD	8.179	9.135
	Median	0.00	0.00
	Min.	-19.5	-19.5
	Max.	19.5	19.5

F approach.
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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Total Score

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Score	n	437	446
		Mean	1.23	1.22
		SD	0.705	0.740
		Median	1.16	1.08
		Min.	0.0	0.0
		Max.	3.7	4.0
Day 7	Score	n	470	463
		Mean	0.75	0.52
		SD	0.609	0.595
		Median	0.63	0.34
		Min.	0.0	0.0
		Max.	3.0	4.0
	Change from Baseline	n	399	412
		Mean	-0.51	-0.73
		SD	0.600	0.665
		Median	-0.41	-0.63
		Min.	-3.0	-3.4
		Max.	1.1	1.6

approach.

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Total Score

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 14	Score	n	444	441
		Mean	0.41	0.29
		SD	0.482	0.420
		Median	0.25	0.13
		Min.	0.0	0.0
		Max.	2.7	3.2
	Change from Baseline	n	373	385
		Mean	-0.84	-0.94
		SD	0.655	0.677
		Median	-0.75	-0.84
		Min.	-3.3	-3.4
		Max.	0.6	0.8
Day 21	Score	n	409	433
		Mean	0.29	0.21
		SD	0.429	0.345
		Median	0.13	0.06
		Min.	0.0	0.0
		Max.	2.8	3.2
	Change from Baseline	n	345	379
		Mean	-0.97	-1.02
		SD	0.667	0.707
		Median	-0.91	-0.91
		Min.	-3.3	-3.4
		Max.	0.5	1.0

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Total Score

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	Score	n	300	294
		Mean	0.22	0.16
		SD	0.349	0.320
		Median	0.06	0.00
		Min.	0.0	0.0
		Max.	2.1	3.0
	Change from Baseline	n	267	265
		Mean	-1.05	-1.10
		SD	0.658	0.736
		Median	-0.94	-1.03
		Min.	-3.3	-3.5
		Max.	0.4	0.4

approach.

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Nose

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Score	n	439	446
		Mean	1.43	1.30
		SD	0.909	0.931
		Median	1.25	1.25
		Min.	0.0	0.0
		Max.	4.0	4.0
Day 7	Score	n	471	463
		Mean	0.83	0.60
		SD	0.752	0.700
		Median	0.75	0.50
		Min.	0.0	0.0
		Max.	3.5	4.0
	Change from Baseline	n	401	412
		Mean	-0.64	-0.73
		SD	0.859	0.896
		Median	-0.50	-0.75
		Min.	-3.8	-3.8
		Max.	2.5	2.0

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Nose

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 14	Score	n	444	441
		Mean	0.45	0.37
		SD	0.595	0.537
		Median	0.25	0.25
		Min.	0.0	0.0
		Max.	2.8	3.3
	Change from Baseline	n	375	385
		Mean	-0.98	-0.95
		SD	0.921	0.900
		Median	-1.00	-0.75
		Min.	-3.8	-3.8
		Max.	1.0	1.8
Day 21	Score	n	409	433
		Mean	0.34	0.28
		SD	0.526	0.451
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.5	3.0
	Change from Baseline	n	347	379
		Mean	-1.10	-1.03
		SD	0.942	0.931
		Median	-1.00	-1.00
		Min.	-3.8	-4.0
		Max.	2.0	1.5

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Nose

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	Score	n	300	295
		Mean	0.29	0.22
		SD	0.514	0.382
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	2.8	3.0
	Change from Baseline	n	268	266
		Mean	-1.17	-1.15
		SD	0.912	0.957
		Median	-1.00	-1.00
		Min.	-3.8	-4.0
		Max.	1.3	1.0

approach.

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Throat

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Score	n	439	446
		Mean	1.05	1.03
		SD	1.005	1.014
		Median	0.67	0.67
		Min.	0.0	0.0
		Max.	4.0	4.0
Day 7	Score	n	471	463
		Mean	0.52	0.38
		SD	0.764	0.708
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.7	4.0
	Change from Baseline	n	401	412
		Mean	-0.57	-0.68
		SD	0.864	0.952
		Median	-0.33	-0.33
		Min.	-4.0	-4.0
		Max.	3.0	2.3

approach.

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Throat

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 14	Score	n	444	441
		Mean	0.27	0.18
		SD	0.565	0.434
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.7	3.0
	Change from Baseline	n	375	385
		Mean	-0.81	-0.87
		SD	0.919	0.956
		Median	-0.67	-0.67
		Min.	-4.0	-4.0
		Max.	1.0	2.0
Day 21	Score	n	409	433
		Mean	0.20	0.12
		SD	0.506	0.387
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.7	4.0
	Change from Baseline	n	347	379
		Mean	-0.89	-0.90
		SD	0.965	0.997
		Median	-0.67	-0.67
		Min.	-3.7	-4.0
		Max.	1.7	1.7

approach.

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Throat

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	Score	n	300	295
		Mean	0.13	0.11
		SD	0.393	0.386
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.0	3.7
	Change from Baseline	n	268	266
		Mean	-0.95	-0.96
		SD	0.935	1.044
		Median	-0.67	-0.67
		Min.	-4.0	-4.0
		Max.	1.0	2.7

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Eyes

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Score	n	439	446
		Mean	0.91	0.83
		SD	0.898	0.946
		Median	0.67	0.33
		Min.	0.0	0.0
		Max.	4.0	4.0
Day 7	Score	n	471	463
		Mean	0.51	0.32
		SD	0.694	0.664
		Median	0.33	0.00
		Min.	0.0	0.0
		Max.	4.0	4.0
	Change from Baseline	n	401	412
		Mean	-0.44	-0.53
		SD	0.898	0.866
		Median	-0.33	-0.33
		Min.	-3.3	-3.7
		Max.	2.0	2.0

approach.

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Eyes

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 14	Score	n	444	441
		Mean	0.27	0.19
		SD	0.526	0.453
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.0	3.7
	Change from Baseline	n	375	385
		Mean	-0.66	-0.64
		SD	0.901	0.887
		Median	-0.33	-0.33
		Min.	-3.3	-4.0
		Max.	2.7	2.0
Day 21	Score	n	409	433
		Mean	0.21	0.13
		SD	0.499	0.411
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.0	3.7
	Change from Baseline	n	347	379
		Mean	-0.73	-0.70
		SD	0.903	0.918
		Median	-0.67	-0.33
		Min.	-3.3	-4.0
		Max.	1.3	2.0

approach.

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Eyes

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	Score	n	300	295
		Mean	0.15	0.09
		SD	0.419	0.357
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.0	3.7
	Change from Baseline	n	268	266
		Mean	-0.82	-0.78
		SD	0.882	0.962
		Median	-0.67	-0.33
		Min.	-3.3	-4.0
		Max.	1.0	2.0

approach.

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Chest/Respiratory

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Score	n	439	446
		Mean	1.24	1.30
		SD	0.821	0.853
		Median	1.14	1.14
		Min.	0.0	0.0
		Max.	4.0	4.0
Day 7	Score	n	471	463
		Mean	0.91	0.64
		SD	0.768	0.724
		Median	0.71	0.43
		Min.	0.0	0.0
		Max.	4.0	4.0
	Change from Baseline	n	401	412
		Mean	-0.35	-0.66
		SD	0.690	0.773
		Median	-0.29	-0.57
		Min.	-3.0	-3.4
		Max.	2.0	2.0

approach.

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Chest/Respiratory

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 14	Score	n	444	441
		Mean	0.54	0.39
		SD	0.622	0.547
		Median	0.43	0.14
		Min.	0.0	0.0
		Max.	2.9	3.0
	Change from Baseline	n	375	385
		Mean	-0.70	-0.89
		SD	0.767	0.795
		Median	-0.57	-0.86
		Min.	-3.1	-3.6
		Max.	1.4	1.4
Day 21	Score	n	409	433
		Mean	0.40	0.27
		SD	0.582	0.455
		Median	0.14	0.00
		Min.	0.0	0.0
		Max.	3.1	3.1
	Change from Baseline	n	347	379
		Mean	-0.85	-1.01
		SD	0.815	0.794
		Median	-0.71	-0.86
		Min.	-3.1	-3.7
		Max.	2.0	1.1

approach.

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Chest/Respiratory

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	Score	n	300	295
		Mean	0.28	0.22
		SD	0.460	0.435
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	2.4	3.0
	Change from Baseline	n	268	266
		Mean	-0.98	-1.13
		SD	0.802	0.851
		Median	-0.86	-1.00
		Min.	-3.1	-3.9
		Max.	0.7	1.3

approach.

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Gastrointestinal

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Score	n	437	446
		Mean	0.75	0.79
		SD	0.788	0.833
		Median	0.50	0.50
		Min.	0.0	0.0
		Max.	3.8	4.0
Day 7	Score	n	470	463
		Mean	0.44	0.29
		SD	0.607	0.540
		Median	0.25	0.00
		Min.	0.0	0.0
		Max.	3.8	4.0
	Change from Baseline	n	399	412
		Mean	-0.34	-0.51
		SD	0.698	0.779
		Median	-0.25	-0.25
		Min.	-3.5	-4.0
		Max.	1.5	2.0

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Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Gastrointestinal

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 14	Score	n	444	441
		Mean	0.21	0.14
		SD	0.454	0.350
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.3	2.8
	Change from Baseline	n	373	385
		Mean	-0.56	-0.66
		SD	0.720	0.764
		Median	-0.25	-0.50
		Min.	-3.5	-4.0
		Max.	1.5	1.5
Day 21	Score	n	409	433
		Mean	0.11	0.08
		SD	0.273	0.285
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	1.8	3.0
	Change from Baseline	n	345	379
		Mean	-0.66	-0.69
		SD	0.741	0.795
		Median	-0.50	-0.50
		Min.	-3.5	-4.0
		Max.	1.5	1.0

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Gastrointestinal

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	Score	n	300	294
		Mean	0.09	0.08
		SD	0.262	0.300
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	2.0	3.0
	Change from Baseline	n	267	265
		Mean	-0.68	-0.74
		SD	0.752	0.828
		Median	-0.50	-0.50
		Min.	-3.8	-4.0
		Max.	0.5	1.3

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Body/Systemic

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Score	n	438	446
		Mean	1.45	1.47
		SD	0.863	0.899
		Median	1.36	1.36
		Min.	0.0	0.0
		Max.	3.9	4.0
Day 7	Score	n	470	463
		Mean	0.86	0.58
		SD	0.759	0.700
		Median	0.67	0.36
		Min.	0.0	0.0
		Max.	3.6	4.0
	Change from Baseline	n	400	412
		Mean	-0.63	-0.92
		SD	0.789	0.828
		Median	-0.55	-0.91
		Min.	-3.3	-3.6
		Max.	1.5	2.0

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Body/Systemic

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 14	Score	n	444	441
		Mean	0.45	0.31
		SD	0.571	0.509
		Median	0.27	0.09
		Min.	0.0	0.0
		Max.	2.8	3.5
	Change from Baseline	n	374	385
		Mean	-1.04	-1.18
		SD	0.839	0.865
		Median	-1.00	-1.18
		Min.	-3.6	-3.9
		Max.	1.1	1.3
Day 21	Score	n	409	433
		Mean	0.31	0.23
		SD	0.492	0.416
		Median	0.09	0.00
		Min.	0.0	0.0
		Max.	2.8	3.5
	Change from Baseline	n	346	379
		Mean	-1.20	-1.25
		SD	0.811	0.883
		Median	-1.18	-1.18
		Min.	-3.6	-3.9
		Max.	0.9	0.9

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Body/Systemic

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	Score	n	300	295
		Mean	0.24	0.16
		SD	0.409	0.360
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	2.3	3.0
	Change from Baseline	n	268	266
		Mean	-1.27	-1.34
		SD	0.798	0.871
		Median	-1.18	-1.27
		Min.	-3.8	-3.9
		Max.	0.5	0.5

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Sense

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Score	n	437	446
		Mean	0.51	0.52
		SD	0.462	0.473
		Median	0.50	0.50
		Min.	0.0	0.0
		Max.	1.0	1.0
Day 7	Score	n	470	463
		Mean	0.46	0.37
		SD	0.475	0.461
		Median	0.50	0.00
		Min.	0.0	0.0
		Max.	1.0	1.0
	Change from Baseline	n	399	412
		Mean	-0.07	-0.17
		SD	0.479	0.536
		Median	0.00	0.00
		Min.	-1.0	-1.0
		Max.	1.0	1.0

approach.

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Sense

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 14	Score	n	444	441
		Mean	0.29	0.22
		SD	0.429	0.396
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	1.0	1.0
	Change from Baseline	n	373	385
		Mean	-0.22	-0.31
		SD	0.529	0.551
		Median	0.00	0.00
		Min.	-1.0	-1.0
		Max.	1.0	1.0
Day 21	Score	n	409	433
		Mean	0.21	0.16
		SD	0.388	0.356
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	1.0	1.0
	Change from Baseline	n	345	379
		Mean	-0.31	-0.36
		SD	0.540	0.530
		Median	0.00	0.00
		Min.	-1.0	-1.0
		Max.	1.0	1.0

approach.

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.7
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Sense

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	Score	n	300	295
		Mean	0.13	0.11
		SD	0.312	0.298
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	1.0	1.0
	Change from Baseline	n	267	266
		Mean	-0.43	-0.45
		SD	0.529	0.530
		Median	-0.50	-0.50
		Min.	-1.0	-1.0
		Max.	1.0	1.0

approach.

Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Total Score

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 1	n	529		528	
	Available	437	(83%)	446	(84%)
	Incomplete questionnaire	2	(<1%)	0	
	Missing questionnaire	90	(17%)	82	(16%)
Day 2	n	528		523	
	Available	356	(67%)	354	(68%)
	Incomplete questionnaire	2	(<1%)	2	(<1%)
	Missing questionnaire	170	(32%)	167	(32%)
Day 3	n	527		523	
	Available	321	(61%)	330	(63%)
	Incomplete questionnaire	3	(<1%)	3	(<1%)
	Missing questionnaire	203	(39%)	190	(36%)
Day 4	n	526		523	
	Available	324	(62%)	309	(59%)
	Incomplete questionnaire	2	(<1%)	0	
	Missing questionnaire	200	(38%)	214	(41%)
Day 5	n	526		523	
	Available	320	(61%)	313	(60%)
	Incomplete questionnaire	4	(<1%)	1	(<1%)
	Missing questionnaire	202	(38%)	209	(40%)
Day 6	n	525		522	
	Available	309	(59%)	301	(58%)
	Incomplete questionnaire	1	(<1%)	1	(<1%)
	Missing questionnaire	215	(41%)	220	(42%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Total Score

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 7	n	525		522	
	Available	292	(56%)	296	(57%)
	Incomplete questionnaire	2	(<1%)	2	(<1%)
	Missing questionnaire	231	(44%)	224	(43%)
Day 8	n	525		522	
	Available	308	(59%)	299	(57%)
	Incomplete questionnaire	2	(<1%)	0	
	Missing questionnaire	215	(41%)	223	(43%)
Day 9	n	525		522	
	Available	290	(55%)	284	(54%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	235	(45%)	238	(46%)
Day 10	n	525		522	
	Available	288	(55%)	281	(54%)
	Incomplete questionnaire	2	(<1%)	0	
	Missing questionnaire	235	(45%)	241	(46%)
Day 11	n	525		522	
	Available	286	(54%)	295	(57%)
	Incomplete questionnaire	2	(<1%)	2	(<1%)
	Missing questionnaire	237	(45%)	225	(43%)
Day 12	n	524		522	
	Available	272	(52%)	275	(53%)
	Incomplete questionnaire	1	(<1%)	1	(<1%)
	Missing questionnaire	251	(48%)	246	(47%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Total Score

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 13	n	524		522	
	Available	278	(53%)	276	(53%)
	Incomplete questionnaire	0		1	(<1%)
	Missing questionnaire	246	(47%)	245	(47%)
Day 14	n	524		522	
	Available	288	(55%)	265	(51%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	236	(45%)	257	(49%)
Day 15	n	524		522	
	Available	311	(59%)	319	(61%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	213	(41%)	203	(39%)
Day 16	n	523		521	
	Available	279	(53%)	279	(54%)
	Incomplete questionnaire	1	(<1%)	1	(<1%)
	Missing questionnaire	243	(46%)	241	(46%)
Day 17	n	521		521	
	Available	249	(48%)	263	(50%)
	Incomplete questionnaire	1	(<1%)	0	
	Missing questionnaire	271	(52%)	258	(50%)
Day 18	n	521		521	
	Available	248	(48%)	264	(51%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	273	(52%)	257	(49%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Total Score

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 19	n	521		521	
	Available	254	(49%)	270	(52%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	267	(51%)	251	(48%)
Day 20	n	521		521	
	Available	261	(50%)	262	(50%)
	Incomplete questionnaire	0		1	(<1%)
	Missing questionnaire	260	(50%)	258	(50%)
Day 21	n	520		521	
	Available	250	(48%)	262	(50%)
	Incomplete questionnaire	1	(<1%)	0	
	Missing questionnaire	269	(52%)	259	(50%)

Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Nose

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 1	n	529		528	
	Available	439	(83%)	446	(84%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	90	(17%)	82	(16%)
Day 2	n	528		523	
	Available	358	(68%)	355	(68%)
	Incomplete questionnaire	0		1	(<1%)
	Missing questionnaire	170	(32%)	167	(32%)
Day 3	n	527		523	
	Available	324	(61%)	333	(64%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	203	(39%)	190	(36%)
Day 4	n	526		523	
	Available	326	(62%)	309	(59%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	200	(38%)	214	(41%)
Day 5	n	526		523	
	Available	324	(62%)	314	(60%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	202	(38%)	209	(40%)
Day 6	n	525		522	
	Available	310	(59%)	302	(58%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	215	(41%)	220	(42%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Nose

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 7	n	525		522	
	Available	294	(56%)	298	(57%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	231	(44%)	224	(43%)
Day 8	n	525		522	
	Available	310	(59%)	299	(57%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	215	(41%)	223	(43%)
Day 9	n	525		522	
	Available	290	(55%)	284	(54%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	235	(45%)	238	(46%)
Day 10	n	525		522	
	Available	290	(55%)	281	(54%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	235	(45%)	241	(46%)
Day 11	n	525		522	
	Available	288	(55%)	297	(57%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	237	(45%)	225	(43%)
Day 12	n	524		522	
	Available	273	(52%)	276	(53%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	251	(48%)	246	(47%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Nose

Visit		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 13	n	524	522
	Available	278 (53%)	277 (53%)
	Incomplete questionnaire	0	0
	Missing questionnaire	246 (47%)	245 (47%)
Day 14	n	524	522
	Available	288 (55%)	265 (51%)
	Incomplete questionnaire	0	0
	Missing questionnaire	236 (45%)	257 (49%)
Day 15	n	524	522
	Available	311 (59%)	319 (61%)
	Incomplete questionnaire	0	0
	Missing questionnaire	213 (41%)	203 (39%)
Day 16	n	523	521
	Available	279 (53%)	279 (54%)
	Incomplete questionnaire	1 (<1%)	1 (<1%)
	Missing questionnaire	243 (46%)	241 (46%)
Day 17	n	521	521
	Available	250 (48%)	263 (50%)
	Incomplete questionnaire	0	0
	Missing questionnaire	271 (52%)	258 (50%)
Day 18	n	521	521
	Available	248 (48%)	264 (51%)
	Incomplete questionnaire	0	0
	Missing questionnaire	273 (52%)	257 (49%)

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Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Nose

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 19	n	521		521	
	Available	254	(49%)	270	(52%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	267	(51%)	251	(48%)
Day 20	n	521		521	
	Available	261	(50%)	263	(50%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	260	(50%)	258	(50%)
Day 21	n	520		521	
	Available	251	(48%)	262	(50%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	269	(52%)	259	(50%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Throat

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 1	n	529		528	
	Available	439	(83%)	446	(84%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	90	(17%)	82	(16%)
Day 2	n	528		523	
	Available	358	(68%)	355	(68%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	170	(32%)	168	(32%)
Day 3	n	527		523	
	Available	324	(61%)	333	(64%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	203	(39%)	190	(36%)
Day 4	n	526		523	
	Available	326	(62%)	309	(59%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	200	(38%)	214	(41%)
Day 5	n	526		523	
	Available	324	(62%)	314	(60%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	202	(38%)	209	(40%)
Day 6	n	525		522	
	Available	310	(59%)	302	(58%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	215	(41%)	220	(42%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Throat

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 7	n	525		522	
	Available	294	(56%)	298	(57%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	231	(44%)	224	(43%)
Day 8	n	525		522	
	Available	310	(59%)	299	(57%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	215	(41%)	223	(43%)
Day 9	n	525		522	
	Available	290	(55%)	284	(54%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	235	(45%)	238	(46%)
Day 10	n	525		522	
	Available	290	(55%)	281	(54%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	235	(45%)	241	(46%)
Day 11	n	525		522	
	Available	288	(55%)	297	(57%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	237	(45%)	225	(43%)
Day 12	n	524		522	
	Available	273	(52%)	276	(53%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	251	(48%)	246	(47%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Throat

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 13	n	524		522	
	Available	278	(53%)	277	(53%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	246	(47%)	245	(47%)
Day 14	n	524		522	
	Available	288	(55%)	265	(51%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	236	(45%)	257	(49%)
Day 15	n	524		522	
	Available	311	(59%)	319	(61%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	213	(41%)	203	(39%)
Day 16	n	523		521	
	Available	279	(53%)	279	(54%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	244	(47%)	242	(46%)
Day 17	n	521		521	
	Available	250	(48%)	263	(50%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	271	(52%)	258	(50%)
Day 18	n	521		521	
	Available	248	(48%)	264	(51%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	273	(52%)	257	(49%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Throat

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 19	n	521		521	
	Available	254	(49%)	270	(52%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	267	(51%)	251	(48%)
Day 20	n	521		521	
	Available	261	(50%)	263	(50%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	260	(50%)	258	(50%)
Day 21	n	520		521	
	Available	251	(48%)	262	(50%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	269	(52%)	259	(50%)

Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Eyes

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 1	n	529		528	
	Available	439	(83%)	446	(84%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	90	(17%)	82	(16%)
Day 2	n	528		523	
	Available	358	(68%)	355	(68%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	170	(32%)	168	(32%)
Day 3	n	527		523	
	Available	324	(61%)	333	(64%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	203	(39%)	190	(36%)
Day 4	n	526		523	
	Available	326	(62%)	309	(59%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	200	(38%)	214	(41%)
Day 5	n	526		523	
	Available	324	(62%)	314	(60%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	202	(38%)	209	(40%)
Day 6	n	525		522	
	Available	310	(59%)	302	(58%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	215	(41%)	220	(42%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Eyes

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 7	n	525		522	
	Available	294	(56%)	297	(57%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	231	(44%)	225	(43%)
Day 8	n	525		522	
	Available	310	(59%)	299	(57%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	215	(41%)	223	(43%)
Day 9	n	525		522	
	Available	290	(55%)	284	(54%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	235	(45%)	238	(46%)
Day 10	n	525		522	
	Available	290	(55%)	281	(54%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	235	(45%)	241	(46%)
Day 11	n	525		522	
	Available	288	(55%)	297	(57%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	237	(45%)	225	(43%)
Day 12	n	524		522	
	Available	273	(52%)	276	(53%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	251	(48%)	246	(47%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Eyes

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 13	n	524		522	
	Available	278	(53%)	277	(53%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	246	(47%)	245	(47%)
Day 14	n	524		522	
	Available	288	(55%)	265	(51%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	236	(45%)	257	(49%)
Day 15	n	524		522	
	Available	311	(59%)	319	(61%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	213	(41%)	203	(39%)
Day 16	n	523		521	
	Available	279	(53%)	279	(54%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	244	(47%)	242	(46%)
Day 17	n	521		521	
	Available	250	(48%)	263	(50%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	271	(52%)	258	(50%)
Day 18	n	521		521	
	Available	248	(48%)	264	(51%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	273	(52%)	257	(49%)

Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Eyes

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 19	n	521		521	
	Available	254	(49%)	270	(52%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	267	(51%)	251	(48%)
Day 20	n	521		521	
	Available	261	(50%)	263	(50%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	260	(50%)	258	(50%)
Day 21	n	520		521	
	Available	251	(48%)	262	(50%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	269	(52%)	259	(50%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Chest/Respiratory

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 1	n	529		528	
	Available	439	(83%)	446	(84%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	90	(17%)	82	(16%)
Day 2	n	528		523	
	Available	358	(68%)	355	(68%)
	Incomplete questionnaire	0		1	(<1%)
	Missing questionnaire	170	(32%)	167	(32%)
Day 3	n	527		523	
	Available	324	(61%)	333	(64%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	203	(39%)	190	(36%)
Day 4	n	526		523	
	Available	326	(62%)	309	(59%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	200	(38%)	214	(41%)
Day 5	n	526		523	
	Available	324	(62%)	314	(60%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	202	(38%)	209	(40%)
Day 6	n	525		522	
	Available	310	(59%)	302	(58%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	215	(41%)	220	(42%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Chest/Respiratory

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 7	n	525		522	
	Available	294	(56%)	298	(57%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	231	(44%)	224	(43%)
Day 8	n	525		522	
	Available	310	(59%)	299	(57%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	215	(41%)	223	(43%)
Day 9	n	525		522	
	Available	290	(55%)	284	(54%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	235	(45%)	238	(46%)
Day 10	n	525		522	
	Available	290	(55%)	281	(54%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	235	(45%)	241	(46%)
Day 11	n	525		522	
	Available	288	(55%)	297	(57%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	237	(45%)	225	(43%)
Day 12	n	524		522	
	Available	273	(52%)	276	(53%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	251	(48%)	246	(47%)

Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Chest/Respiratory

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 13	n	524		522	
	Available	278	(53%)	277	(53%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	246	(47%)	245	(47%)
Day 14	n	524		522	
	Available	288	(55%)	265	(51%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	236	(45%)	257	(49%)
Day 15	n	524		522	
	Available	311	(59%)	319	(61%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	213	(41%)	203	(39%)
Day 16	n	523		521	
	Available	279	(53%)	279	(54%)
	Incomplete questionnaire	1	(<1%)	1	(<1%)
	Missing questionnaire	243	(46%)	241	(46%)
Day 17	n	521		521	
	Available	250	(48%)	263	(50%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	271	(52%)	258	(50%)
Day 18	n	521		521	
	Available	248	(48%)	264	(51%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	273	(52%)	257	(49%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Chest/Respiratory

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 19	n	521		521	
	Available	254	(49%)	270	(52%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	267	(51%)	251	(48%)
Day 20	n	521		521	
	Available	261	(50%)	263	(50%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	260	(50%)	258	(50%)
Day 21	n	520		521	
	Available	251	(48%)	262	(50%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	269	(52%)	259	(50%)

Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Gastrointestinal

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 1	n	529		528	
	Available	437	(83%)	446	(84%)
	Incomplete questionnaire	2	(<1%)	0	
	Missing questionnaire	90	(17%)	82	(16%)
Day 2	n	528		523	
	Available	356	(67%)	354	(68%)
	Incomplete questionnaire	2	(<1%)	2	(<1%)
	Missing questionnaire	170	(32%)	167	(32%)
Day 3	n	527		523	
	Available	321	(61%)	330	(63%)
	Incomplete questionnaire	3	(<1%)	3	(<1%)
	Missing questionnaire	203	(39%)	190	(36%)
Day 4	n	526		523	
	Available	324	(62%)	309	(59%)
	Incomplete questionnaire	2	(<1%)	0	
	Missing questionnaire	200	(38%)	214	(41%)
Day 5	n	526		523	
	Available	321	(61%)	313	(60%)
	Incomplete questionnaire	3	(<1%)	1	(<1%)
	Missing questionnaire	202	(38%)	209	(40%)
Day 6	n	525		522	
	Available	309	(59%)	301	(58%)
	Incomplete questionnaire	1	(<1%)	1	(<1%)
	Missing questionnaire	215	(41%)	220	(42%)

Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Gastrointestinal

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 7	n	525		522	
	Available	292	(56%)	297	(57%)
	Incomplete questionnaire	2	(<1%)	1	(<1%)
	Missing questionnaire	231	(44%)	224	(43%)
Day 8	n	525		522	
	Available	308	(59%)	299	(57%)
	Incomplete questionnaire	2	(<1%)	0	
	Missing questionnaire	215	(41%)	223	(43%)
Day 9	n	525		522	
	Available	290	(55%)	284	(54%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	235	(45%)	238	(46%)
Day 10	n	525		522	
	Available	289	(55%)	281	(54%)
	Incomplete questionnaire	1	(<1%)	0	
	Missing questionnaire	235	(45%)	241	(46%)
Day 11	n	525		522	
	Available	286	(54%)	295	(57%)
	Incomplete questionnaire	2	(<1%)	2	(<1%)
	Missing questionnaire	237	(45%)	225	(43%)
Day 12	n	524		522	
	Available	272	(52%)	275	(53%)
	Incomplete questionnaire	1	(<1%)	1	(<1%)
	Missing questionnaire	251	(48%)	246	(47%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Gastrointestinal

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 13	n	524		522	
	Available	278	(53%)	276	(53%)
	Incomplete questionnaire	0		1	(<1%)
	Missing questionnaire	246	(47%)	245	(47%)
Day 14	n	524		522	
	Available	288	(55%)	265	(51%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	236	(45%)	257	(49%)
Day 15	n	524		522	
	Available	311	(59%)	319	(61%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	213	(41%)	203	(39%)
Day 16	n	523		521	
	Available	279	(53%)	279	(54%)
	Incomplete questionnaire	1	(<1%)	1	(<1%)
	Missing questionnaire	243	(46%)	241	(46%)
Day 17	n	521		521	
	Available	249	(48%)	263	(50%)
	Incomplete questionnaire	1	(<1%)	0	
	Missing questionnaire	271	(52%)	258	(50%)
Day 18	n	521		521	
	Available	248	(48%)	264	(51%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	273	(52%)	257	(49%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Gastrointestinal

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 19	n	521		521	
	Available	254	(49%)	270	(52%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	267	(51%)	251	(48%)
Day 20	n	521		521	
	Available	261	(50%)	262	(50%)
	Incomplete questionnaire	0		1	(<1%)
	Missing questionnaire	260	(50%)	258	(50%)
Day 21	n	520		521	
	Available	250	(48%)	262	(50%)
	Incomplete questionnaire	1	(<1%)	0	
	Missing questionnaire	269	(52%)	259	(50%)

Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Body/Systemic

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 1	n	529		528	
	Available	438	(83%)	446	(84%)
	Incomplete questionnaire	1	(<1%)	0	
	Missing questionnaire	90	(17%)	82	(16%)
Day 2	n	528		523	
	Available	356	(67%)	355	(68%)
	Incomplete questionnaire	2	(<1%)	1	(<1%)
	Missing questionnaire	170	(32%)	167	(32%)
Day 3	n	527		523	
	Available	321	(61%)	331	(63%)
	Incomplete questionnaire	3	(<1%)	2	(<1%)
	Missing questionnaire	203	(39%)	190	(36%)
Day 4	n	526		523	
	Available	324	(62%)	309	(59%)
	Incomplete questionnaire	2	(<1%)	0	
	Missing questionnaire	200	(38%)	214	(41%)
Day 5	n	526		523	
	Available	320	(61%)	313	(60%)
	Incomplete questionnaire	4	(<1%)	1	(<1%)
	Missing questionnaire	202	(38%)	209	(40%)
Day 6	n	525		522	
	Available	309	(59%)	301	(58%)
	Incomplete questionnaire	1	(<1%)	1	(<1%)
	Missing questionnaire	215	(41%)	220	(42%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Body/Systemic

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 7	n	525		522	
	Available	292	(56%)	297	(57%)
	Incomplete questionnaire	2	(<1%)	1	(<1%)
	Missing questionnaire	231	(44%)	224	(43%)
Day 8	n	525		522	
	Available	308	(59%)	299	(57%)
	Incomplete questionnaire	2	(<1%)	0	
	Missing questionnaire	215	(41%)	223	(43%)
Day 9	n	525		522	
	Available	290	(55%)	284	(54%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	235	(45%)	238	(46%)
Day 10	n	525		522	
	Available	288	(55%)	281	(54%)
	Incomplete questionnaire	2	(<1%)	0	
	Missing questionnaire	235	(45%)	241	(46%)
Day 11	n	525		522	
	Available	287	(55%)	295	(57%)
	Incomplete questionnaire	1	(<1%)	2	(<1%)
	Missing questionnaire	237	(45%)	225	(43%)
Day 12	n	524		522	
	Available	273	(52%)	275	(53%)
	Incomplete questionnaire	0		1	(<1%)
	Missing questionnaire	251	(48%)	246	(47%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Body/Systemic

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 13	n	524		522	
	Available	278	(53%)	277	(53%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	246	(47%)	245	(47%)
Day 14	n	524		522	
	Available	288	(55%)	265	(51%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	236	(45%)	257	(49%)
Day 15	n	524		522	
	Available	311	(59%)	319	(61%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	213	(41%)	203	(39%)
Day 16	n	523		521	
	Available	280	(54%)	280	(54%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	243	(46%)	241	(46%)
Day 17	n	521		521	
	Available	250	(48%)	263	(50%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	271	(52%)	258	(50%)
Day 18	n	521		521	
	Available	248	(48%)	264	(51%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	273	(52%)	257	(49%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Body/Systemic

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 19	n	521		521	
	Available	254	(49%)	270	(52%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	267	(51%)	251	(48%)
Day 20	n	521		521	
	Available	261	(50%)	263	(50%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	260	(50%)	258	(50%)
Day 21	n	520		521	
	Available	250	(48%)	262	(50%)
	Incomplete questionnaire	1	(<1%)	0	
	Missing questionnaire	269	(52%)	259	(50%)

Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Sense

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 1	n	529		528	
	Available	437	(83%)	446	(84%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	92	(17%)	82	(16%)
Day 2	n	528		523	
	Available	356	(67%)	355	(68%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	172	(33%)	168	(32%)
Day 3	n	527		523	
	Available	321	(61%)	330	(63%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	206	(39%)	193	(37%)
Day 4	n	526		523	
	Available	324	(62%)	309	(59%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	202	(38%)	214	(41%)
Day 5	n	526		523	
	Available	321	(61%)	313	(60%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	205	(39%)	210	(40%)
Day 6	n	525		522	
	Available	309	(59%)	301	(58%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	216	(41%)	221	(42%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Sense

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 7	n	525		522	
	Available	292	(56%)	297	(57%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	233	(44%)	225	(43%)
Day 8	n	525		522	
	Available	308	(59%)	299	(57%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	217	(41%)	223	(43%)
Day 9	n	525		522	
	Available	290	(55%)	284	(54%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	235	(45%)	238	(46%)
Day 10	n	525		522	
	Available	289	(55%)	281	(54%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	236	(45%)	241	(46%)
Day 11	n	525		522	
	Available	287	(55%)	295	(57%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	238	(45%)	227	(43%)
Day 12	n	524		522	
	Available	273	(52%)	275	(53%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	251	(48%)	247	(47%)

Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Sense

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 13	n	524		522	
	Available	278	(53%)	277	(53%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	246	(47%)	245	(47%)
Day 14	n	524		522	
	Available	288	(55%)	265	(51%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	236	(45%)	257	(49%)
Day 15	n	524		522	
	Available	311	(59%)	319	(61%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	213	(41%)	203	(39%)
Day 16	n	523		521	
	Available	280	(54%)	280	(54%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	243	(46%)	241	(46%)
Day 17	n	521		521	
	Available	250	(48%)	263	(50%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	271	(52%)	258	(50%)
Day 18	n	521		521	
	Available	248	(48%)	264	(51%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	273	(52%)	257	(49%)

Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Sense

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 19	n	521		521	
	Available	254	(49%)	270	(52%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	267	(51%)	251	(48%)
Day 20	n	521		521	
	Available	261	(50%)	263	(50%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	260	(50%)	258	(50%)
Day 21	n	520		521	
	Available	250	(48%)	262	(50%)
	Incomplete questionnaire	0		0	
	Missing questionnaire	270	(52%)	259	(50%)

Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Symptom Alleviation Response

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 1	n	529		528	
	Available	433	(82%)	445	(84%)
	Incomplete questionnaire	6	(1%)	1	(<1%)
	Missing questionnaire	90	(17%)	82	(16%)
Day 2	n	528		523	
	Available	354	(67%)	353	(67%)
	Incomplete questionnaire	4	(<1%)	3	(<1%)
	Missing questionnaire	170	(32%)	167	(32%)
Day 3	n	527		523	
	Available	319	(61%)	330	(63%)
	Incomplete questionnaire	5	(<1%)	3	(<1%)
	Missing questionnaire	203	(39%)	190	(36%)
Day 4	n	526		523	
	Available	323	(61%)	309	(59%)
	Incomplete questionnaire	3	(<1%)	0	
	Missing questionnaire	200	(38%)	214	(41%)
Day 5	n	526		523	
	Available	319	(61%)	313	(60%)
	Incomplete questionnaire	5	(<1%)	1	(<1%)
	Missing questionnaire	202	(38%)	209	(40%)
Day 6	n	525		522	
	Available	306	(58%)	301	(58%)
	Incomplete questionnaire	4	(<1%)	1	(<1%)
	Missing questionnaire	215	(41%)	220	(42%)

Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Symptom Alleviation Response

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 7	n	525		522	
	Available	291	(55%)	297	(57%)
	Incomplete questionnaire	3	(<1%)	1	(<1%)
	Missing questionnaire	231	(44%)	224	(43%)
Day 8	n	525		522	
	Available	307	(58%)	299	(57%)
	Incomplete questionnaire	3	(<1%)	0	
	Missing questionnaire	215	(41%)	223	(43%)
Day 9	n	525		522	
	Available	289	(55%)	283	(54%)
	Incomplete questionnaire	1	(<1%)	1	(<1%)
	Missing questionnaire	235	(45%)	238	(46%)
Day 10	n	525		522	
	Available	286	(54%)	280	(54%)
	Incomplete questionnaire	4	(<1%)	1	(<1%)
	Missing questionnaire	235	(45%)	241	(46%)
Day 11	n	525		522	
	Available	283	(54%)	294	(56%)
	Incomplete questionnaire	5	(<1%)	3	(<1%)
	Missing questionnaire	237	(45%)	225	(43%)
Day 12	n	524		522	
	Available	271	(52%)	273	(52%)
	Incomplete questionnaire	2	(<1%)	3	(<1%)
	Missing questionnaire	251	(48%)	246	(47%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Symptom Alleviation Response

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 13	n	524		522	
	Available	275	(52%)	275	(53%)
	Incomplete questionnaire	3	(<1%)	2	(<1%)
	Missing questionnaire	246	(47%)	245	(47%)
Day 14	n	524		522	
	Available	288	(55%)	263	(50%)
	Incomplete questionnaire	0		2	(<1%)
	Missing questionnaire	236	(45%)	257	(49%)
Day 15	n	524		522	
	Available	309	(59%)	317	(61%)
	Incomplete questionnaire	2	(<1%)	2	(<1%)
	Missing questionnaire	213	(41%)	203	(39%)
Day 16	n	523		521	
	Available	277	(53%)	277	(53%)
	Incomplete questionnaire	3	(<1%)	3	(<1%)
	Missing questionnaire	243	(46%)	241	(46%)
Day 17	n	521		521	
	Available	246	(47%)	262	(50%)
	Incomplete questionnaire	4	(<1%)	1	(<1%)
	Missing questionnaire	271	(52%)	258	(50%)
Day 18	n	521		521	
	Available	245	(47%)	263	(50%)
	Incomplete questionnaire	3	(<1%)	1	(<1%)
	Missing questionnaire	273	(52%)	257	(49%)

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Protocol: 214367
Population: Intent-To-Treat Data as of 27APR2021

Table 4.16
Summary of FLU-PRO Plus Completion Through Day 21

Domain: Symptom Alleviation Response

Visit		Placebo (N=529)		VIR-7831 500mg (N=528)	
Day 19	n	521		521	
	Available	252	(48%)	270	(52%)
	Incomplete questionnaire	2	(<1%)	0	
	Missing questionnaire	267	(51%)	251	(48%)
Day 20	n	521		521	
	Available	261	(50%)	262	(50%)
	Incomplete questionnaire	0		1	(<1%)
	Missing questionnaire	260	(50%)	258	(50%)
Day 21	n	520		521	
	Available	249	(48%)	262	(50%)
	Incomplete questionnaire	2	(<1%)	0	
	Missing questionnaire	269	(52%)	259	(50%)

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.1
Analysis of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Total Score

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 7	n	399	412
	LS Mean (SE)	-1.98 (0.112)	-3.05 (0.111)
	95% C.I.	(-2.20, -1.76)	(-3.27, -2.83)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-1.07 (0.158)
	95% C.I.		(-1.38, -0.76)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.48 (0.071)
	95% C.I.		(-0.62, -0.34)
AUC to Day 14	n	373	385
	LS Mean (SE)	-7.04 (0.236)	-9.40 (0.232)
	95% C.I.	(-7.51, -6.58)	(-9.85, -8.94)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-2.35 (0.331)
	95% C.I.		(-3.00, -1.70)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.52 (0.074)
	95% C.I.		(-0.66, -0.37)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline.
Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.1
Analysis of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Total Score

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 21	n	345	379
	LS Mean (SE)	-13.34 (0.355)	-16.42 (0.338)
	95% C.I.	(-14.03, -12.64)	(-17.09, -15.76)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-3.09 (0.491)
	95% C.I.		(-4.05, -2.12)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.47 (0.075)
	95% C.I.		(-0.62, -0.32)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline.
Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.1
Analysis of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Nose

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 7	n	401	412
	LS Mean (SE)	-2.20 (0.148)	-3.06 (0.146)
	95% C.I.	(-2.49, -1.91)	(-3.34, -2.77)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.86 (0.208)
	95% C.I.		(-1.26, -0.45)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.29 (0.071)
	95% C.I.		(-0.43, -0.15)
AUC to Day 14	n	375	385
	LS Mean (SE)	-7.90 (0.293)	-9.68 (0.289)
	95% C.I.	(-8.48, -7.33)	(-10.25, -9.11)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-1.78 (0.412)
	95% C.I.		(-2.59, -0.97)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.31 (0.073)
	95% C.I.		(-0.46, -0.17)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline.
Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.1
Analysis of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Nose

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 21	n	347	379
	LS Mean (SE)	-14.73 (0.436)	-16.95 (0.417)
	95% C.I.	(-15.58, -13.87)	(-17.77, -16.13)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-2.22 (0.604)
	95% C.I.		(-3.41, -1.04)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.27 (0.075)
	95% C.I.		(-0.42, -0.13)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline.
Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.1
Analysis of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Throat

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 7	n	401	412
	LS Mean (SE)	-2.16 (0.145)	-3.03 (0.143)
	95% C.I.	(-2.44, -1.87)	(-3.31, -2.75)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.88 (0.203)
	95% C.I.		(-1.28, -0.48)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.30 (0.071)
	95% C.I.		(-0.44, -0.16)
AUC to Day 14	n	375	385
	LS Mean (SE)	-6.99 (0.280)	-8.97 (0.276)
	95% C.I.	(-7.54, -6.44)	(-9.51, -8.42)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-1.98 (0.394)
	95% C.I.		(-2.75, -1.21)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.36 (0.073)
	95% C.I.		(-0.51, -0.22)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline.
Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.1
Analysis of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Throat

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 21	n	347	379
	LS Mean (SE)	-12.78 (0.408)	-15.35 (0.390)
	95% C.I.	(-13.58, -11.98)	(-16.11, -14.58)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-2.57 (0.565)
	95% C.I.		(-3.68, -1.46)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.34 (0.075)
	95% C.I.		(-0.48, -0.19)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline.
Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.1
Analysis of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Eyes

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 7	n	401	412
	LS Mean (SE)	-1.54 (0.138)	-2.33 (0.136)
	95% C.I.	(-1.81, -1.27)	(-2.59, -2.06)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.79 (0.194)
	95% C.I.		(-1.17, -0.41)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.28 (0.071)
	95% C.I.		(-0.42, -0.15)
AUC to Day 14	n	375	385
	LS Mean (SE)	-5.29 (0.270)	-7.03 (0.267)
	95% C.I.	(-5.82, -4.76)	(-7.56, -6.51)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-1.74 (0.380)
	95% C.I.		(-2.49, -0.99)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.33 (0.073)
	95% C.I.		(-0.48, -0.19)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline.
Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.1
Analysis of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Eyes

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 21	n	347	379
	LS Mean (SE)	-9.76 (0.408)	-12.07 (0.390)
	95% C.I.	(-10.56, -8.95)	(-12.83, -11.30)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-2.31 (0.565)
	95% C.I.		(-3.42, -1.20)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.30 (0.075)
	95% C.I.		(-0.45, -0.16)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline.
Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.1
Analysis of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Chest/Respiratory

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 7	n	401	412
	LS Mean (SE)	-1.30 (0.132)	-2.60 (0.131)
	95% C.I.	(-1.56, -1.04)	(-2.86, -2.35)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-1.30 (0.186)
	95% C.I.		(-1.66, -0.93)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.49 (0.071)
	95% C.I.		(-0.63, -0.35)
AUC to Day 14	n	375	385
	LS Mean (SE)	-5.45 (0.290)	-8.42 (0.286)
	95% C.I.	(-6.02, -4.88)	(-8.98, -7.85)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-2.97 (0.408)
	95% C.I.		(-3.77, -2.17)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.53 (0.074)
	95% C.I.		(-0.67, -0.38)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline.
Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.1
Analysis of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Chest/Respiratory

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 21	n	347	379
	LS Mean (SE)	-11.05 (0.438)	-15.27 (0.419)
	95% C.I.	(-11.91, -10.19)	(-16.09, -14.44)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-4.22 (0.607)
	95% C.I.		(-5.41, -3.02)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.52 (0.076)
	95% C.I.		(-0.66, -0.37)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline.
Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.1
Analysis of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Gastrointestinal

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 7	n	399	412
	LS Mean (SE)	-1.47 (0.111)	-2.15 (0.109)
	95% C.I.	(-1.69, -1.25)	(-2.36, -1.93)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.68 (0.156)
	95% C.I.		(-0.98, -0.37)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.31 (0.071)
	95% C.I.		(-0.44, -0.17)
AUC to Day 14	n	373	385
	LS Mean (SE)	-4.88 (0.209)	-6.55 (0.206)
	95% C.I.	(-5.30, -4.47)	(-6.95, -6.15)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-1.66 (0.294)
	95% C.I.		(-2.24, -1.09)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.41 (0.073)
	95% C.I.		(-0.56, -0.27)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline.
Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.1
Analysis of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Gastrointestinal

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 21	n	345	379
	LS Mean (SE)	-9.17 (0.299)	-11.03 (0.286)
	95% C.I.	(-9.76, -8.58)	(-11.59, -10.47)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-1.86 (0.414)
	95% C.I.		(-2.67, -1.05)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.33 (0.075)
	95% C.I.		(-0.48, -0.19)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline.
Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.1
Analysis of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Body/Systemic

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 7	n	400	412
	LS Mean (SE)	-2.55 (0.144)	-3.88 (0.142)
	95% C.I.	(-2.83, -2.27)	(-4.16, -3.60)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-1.33 (0.203)
	95% C.I.		(-1.73, -0.93)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.46 (0.071)
	95% C.I.		(-0.60, -0.32)
AUC to Day 14	n	374	385
	LS Mean (SE)	-8.98 (0.292)	-11.75 (0.287)
	95% C.I.	(-9.55, -8.41)	(-12.31, -11.18)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-2.76 (0.410)
	95% C.I.		(-3.57, -1.96)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.49 (0.074)
	95% C.I.		(-0.63, -0.35)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline.
Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.1
Analysis of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Body/Systemic

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 21	n	346	379
	LS Mean (SE)	-16.87 (0.429)	-20.45 (0.410)
	95% C.I.	(-17.71, -16.03)	(-21.26, -19.65)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-3.59 (0.594)
	95% C.I.		(-4.75, -2.42)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.45 (0.075)
	95% C.I.		(-0.60, -0.30)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline.
Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

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Population: Intent-to-Treat Data as of 27APR2021

Table 24.1
Analysis of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Sense

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 7	n	399	412
	LS Mean (SE)	-0.10 (0.090)	-0.55 (0.088)
	95% C.I.	(-0.28, 0.07)	(-0.73, -0.38)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.45 (0.126)
	95% C.I.		(-0.70, -0.21)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.25 (0.071)
	95% C.I.		(-0.39, -0.11)
AUC to Day 14	n	373	385
	LS Mean (SE)	-1.20 (0.207)	-2.39 (0.204)
	95% C.I.	(-1.60, -0.79)	(-2.79, -1.99)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-1.19 (0.291)
	95% C.I.		(-1.76, -0.62)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.30 (0.073)
	95% C.I.		(-0.44, -0.15)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline.
Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.1
Analysis of Average Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Sense

		Placebo (N=529)	VIR-7831 500mg (N=528)
AUC to Day 21	n	345	379
	LS Mean (SE)	-3.32 (0.325)	-4.85 (0.310)
	95% C.I.	(-3.95, -2.68)	(-5.46, -4.24)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-1.53 (0.449)
	95% C.I.		(-2.41, -0.65)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.25 (0.075)
	95% C.I.		(-0.40, -0.11)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline.
Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.2
Analysis of Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Total Score

		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 7	n	399	412
	LS Mean (SE)	0.73 (0.025)	0.51 (0.024)
	95% C.I.	(0.68, 0.77)	(0.46, 0.56)
	LS Mean Change from Baseline (SE)	-0.51 (0.025)	-0.73 (0.024)
	95% C.I.	(-0.56, -0.46)	(-0.78, -0.68)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.22 (0.035)
	95% C.I.		(-0.29, -0.15)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.44 (0.071)
	95% C.I.		(-0.58, -0.30)
Day 14	n	373	385
	LS Mean (SE)	0.39 (0.022)	0.28 (0.021)
	95% C.I.	(0.35, 0.44)	(0.24, 0.33)
	LS Mean Change from Baseline (SE)	-0.84 (0.022)	-0.95 (0.021)
	95% C.I.	(-0.88, -0.79)	(-0.99, -0.91)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.11 (0.030)
	95% C.I.		(-0.17, -0.05)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.26 (0.073)
	95% C.I.		(-0.41, -0.12)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline. Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.2
Analysis of Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Total Score

		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 21	n	345	379
	LS Mean (SE)	0.28 (0.020)	0.21 (0.019)
	95% C.I.	(0.24, 0.32)	(0.17, 0.25)
	LS Mean Change from Baseline (SE)	-0.96 (0.020)	-1.03 (0.019)
	95% C.I.	(-1.00, -0.92)	(-1.07, -0.99)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.07 (0.028)
	95% C.I.		(-0.13, -0.02)
	p-value		0.010
	Corrected Hedge’s g (SE) [1]		-0.19 (0.075)
	95% C.I.		(-0.34, -0.05)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline. Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.2
Analysis of Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Nose

		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 7	n	401	412
	LS Mean (SE)	0.78 (0.032)	0.60 (0.032)
	95% C.I.	(0.72, 0.85)	(0.54, 0.67)
	LS Mean Change from Baseline (SE)	-0.59 (0.032)	-0.77 (0.032)
	95% C.I.	(-0.66, -0.53)	(-0.84, -0.71)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.18 (0.045)
	95% C.I.		(-0.27, -0.09)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.28 (0.070)
	95% C.I.		(-0.42, -0.14)
Day 14	n	375	385
	LS Mean (SE)	0.43 (0.028)	0.37 (0.028)
	95% C.I.	(0.38, 0.49)	(0.32, 0.42)
	LS Mean Change from Baseline (SE)	-0.94 (0.028)	-1.00 (0.028)
	95% C.I.	(-0.99, -0.88)	(-1.05, -0.94)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.06 (0.039)
	95% C.I.		(-0.14, 0.02)
	p-value		0.124
	Corrected Hedge’s g (SE) [1]		-0.11 (0.073)
	95% C.I.		(-0.25, 0.03)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline. Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.2
Analysis of Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Nose

		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 21	n	347	379
	LS Mean (SE)	0.33 (0.026)	0.28 (0.025)
	95% C.I.	(0.27, 0.38)	(0.23, 0.33)
	LS Mean Change from Baseline (SE)	-1.04 (0.026)	-1.08 (0.025)
	95% C.I.	(-1.09, -0.99)	(-1.13, -1.03)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.04 (0.036)
	95% C.I.		(-0.11, 0.03)
	p-value		0.222
	Corrected Hedge’s g (SE) [1]		-0.09 (0.074)
	95% C.I.		(-0.24, 0.05)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline. Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.2
Analysis of Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Throat

		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 7	n	401	412
	LS Mean (SE)	0.49 (0.031)	0.36 (0.030)
	95% C.I.	(0.43, 0.55)	(0.31, 0.42)
	LS Mean Change from Baseline (SE)	-0.56 (0.031)	-0.68 (0.030)
	95% C.I.	(-0.62, -0.50)	(-0.74, -0.62)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.12 (0.043)
	95% C.I.		(-0.21, -0.04)
	p-value		0.005
	Corrected Hedge’s g (SE) [1]		-0.20 (0.070)
	95% C.I.		(-0.34, -0.06)
Day 14	n	375	385
	LS Mean (SE)	0.27 (0.024)	0.16 (0.024)
	95% C.I.	(0.22, 0.32)	(0.12, 0.21)
	LS Mean Change from Baseline (SE)	-0.78 (0.024)	-0.89 (0.024)
	95% C.I.	(-0.83, -0.74)	(-0.94, -0.84)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.10 (0.034)
	95% C.I.		(-0.17, -0.04)
	p-value		0.002
	Corrected Hedge’s g (SE) [1]		-0.22 (0.073)
	95% C.I.		(-0.37, -0.08)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline. Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.2
Analysis of Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Throat

		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 21	n	347	379
	LS Mean (SE)	0.20 (0.024)	0.13 (0.023)
	95% C.I.	(0.15, 0.24)	(0.09, 0.17)
	LS Mean Change from Baseline (SE)	-0.86 (0.024)	-0.92 (0.023)
	95% C.I.	(-0.90, -0.81)	(-0.97, -0.88)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.07 (0.033)
	95% C.I.		(-0.13, 0.00)
	p-value		0.042
	Corrected Hedge’s g (SE) [1]		-0.15 (0.074)
	95% C.I.		(-0.30, -0.01)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline. Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.2
Analysis of Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Eyes

		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 7	n	401	412
	LS Mean (SE)	0.48 (0.030)	0.33 (0.030)
	95% C.I.	(0.42, 0.54)	(0.27, 0.39)
	LS Mean Change from Baseline (SE)	-0.41 (0.030)	-0.56 (0.030)
	95% C.I.	(-0.47, -0.35)	(-0.62, -0.50)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.15 (0.043)
	95% C.I.		(-0.23, -0.07)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.24 (0.070)
	95% C.I.		(-0.38, -0.11)
Day 14	n	375	385
	LS Mean (SE)	0.25 (0.024)	0.20 (0.024)
	95% C.I.	(0.20, 0.30)	(0.15, 0.24)
	LS Mean Change from Baseline (SE)	-0.63 (0.024)	-0.68 (0.024)
	95% C.I.	(-0.67, -0.58)	(-0.73, -0.64)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.06 (0.034)
	95% C.I.		(-0.12, 0.01)
	p-value		0.094
	Corrected Hedge’s g (SE) [1]		-0.12 (0.073)
	95% C.I.		(-0.26, 0.02)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline. Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.2
Analysis of Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Eyes

		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 21	n	347	379
	LS Mean (SE)	0.20 (0.024)	0.14 (0.023)
	95% C.I.	(0.15, 0.25)	(0.10, 0.19)
	LS Mean Change from Baseline (SE)	-0.68 (0.024)	-0.74 (0.023)
	95% C.I.	(-0.73, -0.64)	(-0.79, -0.70)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.06 (0.034)
	95% C.I.		(-0.12, 0.01)
	p-value		0.085
	Corrected Hedge’s g (SE) [1]		-0.13 (0.074)
	95% C.I.		(-0.27, 0.02)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline. Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.2
Analysis of Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Chest/Respiratory

		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 7	n	401	412
	LS Mean (SE)	0.91 (0.030)	0.62 (0.030)
	95% C.I.	(0.85, 0.97)	(0.57, 0.68)
	LS Mean Change from Baseline (SE)	-0.37 (0.030)	-0.65 (0.030)
	95% C.I.	(-0.43, -0.31)	(-0.71, -0.59)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.28 (0.043)
	95% C.I.		(-0.37, -0.20)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.46 (0.071)
	95% C.I.		(-0.60, -0.32)
Day 14	n	375	385
	LS Mean (SE)	0.54 (0.028)	0.38 (0.028)
	95% C.I.	(0.49, 0.60)	(0.33, 0.44)
	LS Mean Change from Baseline (SE)	-0.72 (0.028)	-0.88 (0.028)
	95% C.I.	(-0.77, -0.66)	(-0.93, -0.82)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.16 (0.039)
	95% C.I.		(-0.24, -0.08)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.30 (0.073)
	95% C.I.		(-0.44, -0.15)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline. Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.2
Analysis of Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Chest/Respiratory

		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 21	n	347	379
	LS Mean (SE)	0.40 (0.027)	0.27 (0.026)
	95% C.I.	(0.35, 0.46)	(0.22, 0.32)
	LS Mean Change from Baseline (SE)	-0.86 (0.027)	-1.00 (0.026)
	95% C.I.	(-0.92, -0.81)	(-1.05, -0.95)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.14 (0.037)
	95% C.I.		(-0.21, -0.06)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.27 (0.075)
	95% C.I.		(-0.42, -0.13)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline. Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.2
Analysis of Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Gastrointestinal

		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 7	n	399	412
	LS Mean (SE)	0.41 (0.025)	0.27 (0.024)
	95% C.I.	(0.37, 0.46)	(0.22, 0.32)
	LS Mean Change from Baseline (SE)	-0.36 (0.025)	-0.50 (0.024)
	95% C.I.	(-0.41, -0.31)	(-0.55, -0.45)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.14 (0.035)
	95% C.I.		(-0.21, -0.07)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.29 (0.071)
	95% C.I.		(-0.42, -0.15)
Day 14	n	373	385
	LS Mean (SE)	0.19 (0.018)	0.13 (0.018)
	95% C.I.	(0.16, 0.23)	(0.10, 0.17)
	LS Mean Change from Baseline (SE)	-0.57 (0.018)	-0.64 (0.018)
	95% C.I.	(-0.61, -0.54)	(-0.67, -0.60)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.06 (0.026)
	95% C.I.		(-0.11, -0.01)
	p-value		0.014
	Corrected Hedge’s g (SE) [1]		-0.18 (0.073)
	95% C.I.		(-0.32, -0.04)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline. Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.2
Analysis of Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Gastrointestinal

		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 21	n	345	379
	LS Mean (SE)	0.11 (0.015)	0.09 (0.014)
	95% C.I.	(0.08, 0.13)	(0.06, 0.11)
	LS Mean Change from Baseline (SE)	-0.67 (0.015)	-0.69 (0.014)
	95% C.I.	(-0.70, -0.64)	(-0.71, -0.66)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.02 (0.020)
	95% C.I.		(-0.06, 0.02)
	p-value		0.383
	Corrected Hedge’s g (SE) [1]		-0.06 (0.074)
	95% C.I.		(-0.21, 0.08)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline. Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.2
Analysis of Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Body/Systemic

		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 7	n	400	412
	LS Mean (SE)	0.84 (0.031)	0.56 (0.031)
	95% C.I.	(0.78, 0.90)	(0.50, 0.62)
	LS Mean Change from Baseline (SE)	-0.64 (0.031)	-0.91 (0.031)
	95% C.I.	(-0.70, -0.58)	(-0.98, -0.85)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.28 (0.044)
	95% C.I.		(-0.36, -0.19)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.44 (0.071)
	95% C.I.		(-0.58, -0.30)
Day 14	n	374	385
	LS Mean (SE)	0.43 (0.026)	0.30 (0.026)
	95% C.I.	(0.38, 0.48)	(0.25, 0.35)
	LS Mean Change from Baseline (SE)	-1.04 (0.026)	-1.17 (0.026)
	95% C.I.	(-1.09, -0.99)	(-1.22, -1.12)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.13 (0.037)
	95% C.I.		(-0.20, -0.06)
	p-value		<0.001
	Corrected Hedge’s g (SE) [1]		-0.26 (0.073)
	95% C.I.		(-0.41, -0.12)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline. Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.2
Analysis of Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Body/Systemic

		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 21	n	346	379
	LS Mean (SE)	0.29 (0.023)	0.22 (0.022)
	95% C.I.	(0.25, 0.34)	(0.18, 0.27)
	LS Mean Change from Baseline (SE)	-1.19 (0.023)	-1.26 (0.022)
	95% C.I.	(-1.24, -1.15)	(-1.30, -1.22)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.07 (0.032)
	95% C.I.		(-0.13, -0.01)
	p-value		0.031
	Corrected Hedge’s g (SE) [1]		-0.16 (0.074)
	95% C.I.		(-0.31, -0.01)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline. Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.2
Analysis of Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Sense

		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 7	n	399	412
	LS Mean (SE)	0.46 (0.021)	0.36 (0.021)
	95% C.I.	(0.42, 0.50)	(0.32, 0.40)
	LS Mean Change from Baseline (SE)	-0.07 (0.021)	-0.16 (0.021)
	95% C.I.	(-0.11, -0.03)	(-0.20, -0.12)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.10 (0.030)
	95% C.I.		(-0.15, -0.04)
	p-value		0.001
	Corrected Hedge’s g (SE) [1]		-0.22 (0.070)
	95% C.I.		(-0.36, -0.09)
Day 14	n	373	385
	LS Mean (SE)	0.29 (0.021)	0.21 (0.020)
	95% C.I.	(0.25, 0.33)	(0.17, 0.25)
	LS Mean Change from Baseline (SE)	-0.22 (0.021)	-0.31 (0.020)
	95% C.I.	(-0.27, -0.18)	(-0.35, -0.27)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.08 (0.029)
	95% C.I.		(-0.14, -0.02)
	p-value		0.005
	Corrected Hedge’s g (SE) [1]		-0.20 (0.073)
	95% C.I.		(-0.35, -0.06)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline. Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.2
Analysis of Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Sense

		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 21	n	345	379
	LS Mean (SE)	0.21 (0.020)	0.16 (0.019)
	95% C.I.	(0.17, 0.25)	(0.13, 0.20)
	LS Mean Change from Baseline (SE)	-0.31 (0.020)	-0.36 (0.019)
	95% C.I.	(-0.35, -0.27)	(-0.40, -0.32)
	VIR-7831 500 mg vs. Placebo		
	Difference (SE)		-0.05 (0.027)
	95% C.I.		(-0.10, 0.00)
	p-value		0.072
	Corrected Hedge’s g (SE) [1]		-0.13 (0.074)
	95% C.I.		(-0.28, 0.01)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female) and baseline. Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 24.3
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days

		Placebo (N=529)	VIR-7831 500mg (N=528)
Day 7	Number of subjects with event	31 (6%)	76 (14%)
	Number of subjects censored	4 (<1%)	6 (1%)
	Number of subjects without event	494 (93%)	446 (84%)
	Probability of having event [1]	5.9%	14.5%
	95% C.I.	(4.2%, 8.3%)	(11.8%, 17.9%)
Day 14	Number of subjects with event	104 (20%)	164 (31%)
	Number of subjects censored	5 (<1%)	6 (1%)
	Number of subjects without event	420 (79%)	358 (68%)
	Probability of having event [1]	19.8%	31.4%
	95% C.I.	(16.7%, 23.5%)	(27.6%, 35.6%)
Day 21	Number of subjects with event	178 (34%)	214 (41%)
	Number of subjects censored	351 (66%)	314 (59%)
	Number of subjects without event	0	0
	Probability of having event [1]	34.0%	41.0%
	95% C.I.	(30.1%, 38.2%)	(36.9%, 45.4%)
	First quartile (95% C.I.) time to onset (days)	16 (15,18)	12 (10,13)
	Median (95% C.I.) time to onset (days)	NE (NE,NE)	NE (NE,NE)
	Third quartile (95% C.I.) time to onset (days)	NE (NE,NE)	NE (NE,NE)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with a covariate of treatment.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.3
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		0.74
95% C.I.		(0.61, 0.90)
p-value		0.003

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with a covariate of treatment.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.4
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus

Visit: Day 7

	Placebo (N=529)	VIR-7831 500mg (N=528)
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	31 (6%)	76 (14%)
Not sustained symptom alleviation	498 (94%)	452 (86%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		0.36
95% C.I.		(0.23, 0.56)
p-value		<0.001
Inverse Relative Risk [2]		0.40
95% C.I.		(0.27, 0.59)
p-value		<0.001
Risk Difference (%) [3]		-8.53
95% C.I.		(-12.14, -4.93)
p-value		<0.001

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

PPD

Table 24.4
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus

Visit: Day 14

	Placebo (N=529)	VIR-7831 500mg (N=528)
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	104 (20%)	164 (31%)
Not sustained symptom alleviation	425 (80%)	364 (69%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		0.54
95% C.I.		(0.40, 0.71)
p-value		<0.001
Inverse Relative Risk [2]		0.63
95% C.I.		(0.51, 0.78)
p-value		<0.001
Risk Difference (%) [3]		-11.40
95% C.I.		(-16.60, -6.20)
p-value		<0.001

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.4
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus

Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	178 (34%)	214 (41%)
Not sustained symptom alleviation	351 (66%)	314 (59%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		0.74
95% C.I.		(0.57, 0.95)
p-value		0.019
Inverse Relative Risk [2]		0.83
95% C.I.		(0.71, 0.97)
p-value		0.020
Risk Difference (%) [3]		-6.88
95% C.I.		(-12.69, -1.07)
p-value		0.022

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old) and gender (male, female), using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.5
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 7, Day 14, Day 21 and Day 29

Visit: Day 7

	Placebo (N=529)	VIR-7831 500mg (N=528)
FLU-PRO Plus Responder Status, n (%)		
Responder	142 (27%)	212 (40%)
Non-responder	257 (49%)	200 (38%)
Missing [1]	130 (25%)	116 (22%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.55
95% C.I.		(0.42, 0.71)
p-value		<0.001
Inverse Relative Risk [3]		0.67
95% C.I.		(0.56, 0.80)
p-value		<0.001
Risk Difference (%) [4]		-13.31
95% C.I.		(-18.94, -7.67)
p-value		<0.001

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.5
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 7, Day 14, Day 21 and Day 29

Visit: Day 14

	Placebo (N=529)	VIR-7831 500mg (N=528)
FLU-PRO Plus Responder Status, n (%)		
Responder	222 (42%)	264 (50%)
Non-responder	151 (29%)	121 (23%)
Missing [1]	156 (29%)	143 (27%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.72
95% C.I.		(0.57, 0.92)
p-value		0.009
Inverse Relative Risk [3]		0.84
95% C.I.		(0.74, 0.96)
p-value		0.010
Risk Difference (%) [4]		-8.03
95% C.I.		(-14.02, -2.04)
p-value		0.010

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.5
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 7, Day 14, Day 21 and Day 29

Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
FLU-PRO Plus Responder Status, n (%)		
Responder	233 (44%)	265 (50%)
Non-responder	112 (21%)	114 (22%)
Missing [1]	184 (35%)	149 (28%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.78
95% C.I.		(0.61, 1.00)
p-value		0.046
Inverse Relative Risk [3]		0.88
95% C.I.		(0.77, 1.00)
p-value		0.046
Risk Difference (%) [4]		-6.14
95% C.I.		(-12.15, -0.14)
p-value		0.049

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.5
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 7, Day 14, Day 21 and Day 29

Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
FLU-PRO Plus Responder Status, n (%)		
Responder	190 (36%)	193 (37%)
Non-responder	77 (15%)	72 (14%)
Missing [1]	262 (50%)	263 (50%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.97
95% C.I.		(0.76, 1.25)
p-value		0.830
Inverse Relative Risk [3]		0.98
95% C.I.		(0.84, 1.15)
p-value		0.830
Risk Difference (%) [4]		-0.64
95% C.I.		(-6.43, 5.16)
p-value		0.848

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Protocol: 214367
Population: Intent-to-Treat

Table 34.1
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Week 8 and Week 12

Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
FLU-PRO Plus Responder Status, n (%)		
Responder	209 (40%)	199 (38%)
Non-responder	61 (12%)	80 (15%)
Missing [1]	259 (49%)	249 (47%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.08
95% C.I.		(0.84, 1.38)
p-value		0.544
Inverse Relative Risk [3]		1.05
95% C.I.		(0.90, 1.22)
p-value		0.544
Risk Difference (%) [4]		1.82
95% C.I.		(-4.05, 7.69)
p-value		0.570

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.

PPD

Population: Intent-to-Treat

Table 34.1
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Week 8 and Week 12

Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
FLU-PRO Plus Responder Status, n (%)		
Responder	204 (39%)	184 (35%)
Non-responder	72 (14%)	84 (16%)
Missing [1]	253 (48%)	260 (49%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.17
95% C.I.		(0.91, 1.51)
p-value		0.211
Inverse Relative Risk [3]		1.11
95% C.I.		(0.94, 1.30)
p-value		0.211
Risk Difference (%) [4]		3.71
95% C.I.		(-2.09, 9.52)
p-value		0.226

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Total Score

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Score	n	451	459
		Mean	1.22	1.22
		SD	0.707	0.748
		Median	1.16	1.06
		Min.	0.0	0.0
		Max.	3.7	4.0
Day 7	Score	n	475	474
		Mean	0.75	0.53
		SD	0.613	0.605
		Median	0.63	0.34
		Min.	0.0	0.0
		Max.	3.0	4.0
	Change from Baseline	n	416	430
		Mean	-0.51	-0.71
		SD	0.604	0.673
		Median	-0.41	-0.63
		Min.	-3.0	-3.4
		Max.	1.1	1.6

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Total Score

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Day 14	Score	n	448	448
		Mean	0.40	0.30
		SD	0.482	0.428
		Median	0.25	0.13
		Min.	0.0	0.0
		Max.	2.7	3.2
	Change from Baseline	n	390	402
		Mean	-0.84	-0.92
		SD	0.661	0.685
		Median	-0.75	-0.81
		Min.	-3.3	-3.4
		Max.	0.6	0.8
Day 21	Score	n	415	440
		Mean	0.28	0.21
		SD	0.424	0.358
		Median	0.09	0.06
		Min.	0.0	0.0
		Max.	2.8	3.2
	Change from Baseline	n	360	397
		Mean	-0.97	-1.00
		SD	0.664	0.720
		Median	-0.91	-0.88
		Min.	-3.3	-3.4
		Max.	0.5	1.0

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

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Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Total Score

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Day 29	Score	n	320	319
		Mean	0.21	0.15
		SD	0.342	0.325
		Median	0.06	0.00
		Min.	0.0	0.0
		Max.	2.1	3.0
	Change from Baseline	n	294	293
		Mean	-1.03	-1.08
		SD	0.669	0.742
		Median	-0.91	-0.94
		Min.	-3.3	-3.5
		Max.	0.4	0.4
Week 8	Score	n	301	306
		Mean	0.15	0.15
		SD	0.277	0.311
		Median	0.03	0.02
		Min.	0.0	0.0
		Max.	2.2	2.9
	Change from Baseline	n	270	279
		Mean	-1.17	-1.10
		SD	0.701	0.764
		Median	-1.13	-0.97
		Min.	-3.7	-3.7
		Max.	0.9	0.9

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Total Score

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	Score	n	305	298
		Mean	0.18	0.14
		SD	0.303	0.257
		Median	0.03	0.03
		Min.	0.0	0.0
		Max.	1.6	2.0
	Change from Baseline	n	276	268
		Mean	-1.07	-0.92
		SD	0.689	0.668
		Median	-1.00	-0.92
		Min.	-3.1	-3.3
		Max.	1.1	1.1

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

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Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Nose

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Score	n	453	459
		Mean	1.42	1.29
		SD	0.911	0.933
		Median	1.25	1.25
		Min.	0.0	0.0
		Max.	4.0	4.0
Day 7	Score	n	476	474
		Mean	0.84	0.61
		SD	0.758	0.724
		Median	0.75	0.50
		Min.	0.0	0.0
		Max.	3.5	4.0
	Change from Baseline	n	418	430
		Mean	-0.62	-0.70
		SD	0.872	0.920
		Median	-0.50	-0.50
		Min.	-3.8	-3.8
		Max.	2.5	2.8

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

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Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Nose

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Day 14	Score	n	448	448
		Mean	0.44	0.38
		SD	0.592	0.558
		Median	0.25	0.25
		Min.	0.0	0.0
		Max.	2.8	3.3
	Change from Baseline	n	392	402
		Mean	-0.99	-0.93
		SD	0.930	0.903
		Median	-1.00	-0.75
		Min.	-3.8	-3.8
		Max.	1.0	1.8
Day 21	Score	n	415	440
		Mean	0.33	0.28
		SD	0.525	0.460
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.5	3.0
	Change from Baseline	n	362	397
		Mean	-1.09	-1.01
		SD	0.941	0.931
		Median	-1.00	-1.00
		Min.	-3.8	-4.0
		Max.	2.0	1.5

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

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Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Nose

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Day 29	Score	n	321	320
		Mean	0.30	0.21
		SD	0.517	0.399
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	2.8	3.0
	Change from Baseline	n	296	294
		Mean	-1.14	-1.11
		SD	0.913	0.965
		Median	-1.00	-1.00
		Min.	-3.8	-4.0
		Max.	1.3	1.0
Week 8	Score	n	301	307
		Mean	0.22	0.23
		SD	0.430	0.440
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	2.8	3.0
	Change from Baseline	n	272	279
		Mean	-1.29	-1.07
		SD	0.993	1.016
		Median	-1.25	-1.00
		Min.	-4.0	-4.0
		Max.	1.3	3.0

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Nose

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	Score	n	305	299
		Mean	0.25	0.23
		SD	0.473	0.405
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	2.8	2.5
	Change from Baseline	n	277	269
		Mean	-1.17	-1.00
		SD	0.988	0.946
		Median	-1.25	-1.00
		Min.	-3.8	-3.8
		Max.	1.8	1.8

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

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Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Throat

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Score	n	453	460
		Mean	1.06	1.02
		SD	1.017	1.017
		Median	0.67	0.67
		Min.	0.0	0.0
		Max.	4.0	4.0
Day 7	Score	n	476	474
		Mean	0.52	0.39
		SD	0.765	0.726
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.7	4.0
	Change from Baseline	n	418	431
		Mean	-0.57	-0.65
		SD	0.877	0.975
		Median	-0.33	-0.33
		Min.	-4.0	-4.0
		Max.	3.0	3.3

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Throat

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Day 14	Score	n	448	448
		Mean	0.27	0.18
		SD	0.568	0.448
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.7	3.0
	Change from Baseline	n	392	403
		Mean	-0.81	-0.84
		SD	0.939	0.953
		Median	-0.67	-0.67
		Min.	-4.0	-4.0
		Max.	1.0	2.0
Day 21	Score	n	415	440
		Mean	0.20	0.13
		SD	0.502	0.395
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.7	4.0
	Change from Baseline	n	362	398
		Mean	-0.88	-0.88
		SD	0.965	0.995
		Median	-0.67	-0.67
		Min.	-3.7	-4.0
		Max.	1.7	1.7

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Throat

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Day 29	Score	n	321	320
		Mean	0.13	0.11
		SD	0.410	0.405
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.0	3.7
	Change from Baseline	n	296	295
		Mean	-0.94	-0.92
		SD	0.940	1.027
		Median	-0.67	-0.67
		Min.	-4.0	-4.0
		Max.	1.0	2.7
Week 8	Score	n	302	307
		Mean	0.10	0.10
		SD	0.302	0.349
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	2.3	3.0
	Change from Baseline	n	273	280
		Mean	-1.08	-0.96
		SD	1.039	1.020
		Median	-1.00	-0.67
		Min.	-4.0	-4.0
		Max.	1.0	1.7

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Population: Intent-to-Treat

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Throat

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	Score	n	305	299
		Mean	0.13	0.07
		SD	0.398	0.241
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.0	2.0
	Change from Baseline	n	277	270
		Mean	-0.94	-0.83
		SD	1.020	0.907
		Median	-0.67	-0.67
		Min.	-4.0	-3.7
		Max.	2.0	1.0

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Eyes

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Score	n	453	460
		Mean	0.91	0.83
		SD	0.897	0.950
		Median	0.67	0.50
		Min.	0.0	0.0
		Max.	4.0	4.0
Day 7	Score	n	476	474
		Mean	0.51	0.32
		SD	0.696	0.655
		Median	0.33	0.00
		Min.	0.0	0.0
		Max.	4.0	4.0
	Change from Baseline	n	418	431
		Mean	-0.43	-0.52
		SD	0.904	0.859
		Median	-0.33	-0.33
		Min.	-3.3	-3.7
		Max.	2.0	2.0

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Eyes

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Day 14	Score	n	448	448
		Mean	0.26	0.20
		SD	0.514	0.467
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.0	3.7
	Change from Baseline	n	392	403
		Mean	-0.67	-0.63
		SD	0.897	0.877
		Median	-0.33	-0.33
		Min.	-3.3	-4.0
		Max.	2.7	2.0
Day 21	Score	n	415	440
		Mean	0.20	0.14
		SD	0.480	0.416
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.0	3.7
	Change from Baseline	n	362	398
		Mean	-0.74	-0.69
		SD	0.902	0.921
		Median	-0.67	-0.33
		Min.	-3.3	-4.0
		Max.	1.3	2.0

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Eyes

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Day 29	Score	n	321	320
		Mean	0.16	0.10
		SD	0.421	0.362
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.0	3.7
	Change from Baseline	n	296	295
		Mean	-0.80	-0.76
		SD	0.902	0.960
		Median	-0.67	-0.33
		Min.	-3.3	-4.0
		Max.	1.7	2.0
Week 8	Score	n	302	307
		Mean	0.14	0.15
		SD	0.381	0.445
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	2.3	3.7
	Change from Baseline	n	273	280
		Mean	-0.89	-0.70
		SD	0.971	0.991
		Median	-0.67	-0.33
		Min.	-3.3	-4.0
		Max.	2.3	2.3

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Population: Intent-to-Treat

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Eyes

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	Score	n	305	299
		Mean	0.17	0.14
		SD	0.467	0.407
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	4.0	4.0
	Change from Baseline	n	277	270
		Mean	-0.75	-0.63
		SD	0.965	0.887
		Median	-0.67	-0.33
		Min.	-3.3	-4.0
		Max.	3.3	2.3

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Chest/Respiratory

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Score	n	453	460
		Mean	1.24	1.29
		SD	0.829	0.860
		Median	1.14	1.14
		Min.	0.0	0.0
		Max.	4.0	4.0
Day 7	Score	n	476	474
		Mean	0.91	0.65
		SD	0.767	0.731
		Median	0.71	0.43
		Min.	0.0	0.0
		Max.	4.0	4.0
	Change from Baseline	n	418	431
		Mean	-0.35	-0.64
		SD	0.698	0.785
		Median	-0.29	-0.57
		Min.	-3.0	-3.4
		Max.	2.0	2.0

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Chest/Respiratory

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Day 14	Score	n	448	448
		Mean	0.53	0.40
		SD	0.624	0.550
		Median	0.29	0.14
		Min.	0.0	0.0
		Max.	2.9	3.0
	Change from Baseline	n	392	403
		Mean	-0.71	-0.88
		SD	0.792	0.813
		Median	-0.57	-0.71
		Min.	-3.1	-3.6
		Max.	1.4	1.4
Day 21	Score	n	415	440
		Mean	0.39	0.28
		SD	0.580	0.457
		Median	0.14	0.00
		Min.	0.0	0.0
		Max.	3.1	3.1
	Change from Baseline	n	362	398
		Mean	-0.86	-1.00
		SD	0.827	0.807
		Median	-0.71	-0.86
		Min.	-3.1	-3.7
		Max.	2.0	1.1

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Chest/Respiratory

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Day 29	Score	n	321	320
		Mean	0.27	0.21
		SD	0.449	0.426
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	2.4	3.0
	Change from Baseline	n	296	295
		Mean	-0.98	-1.10
		SD	0.829	0.850
		Median	-0.86	-1.00
		Min.	-3.4	-3.9
		Max.	0.7	1.3
Week 8	Score	n	302	307
		Mean	0.15	0.17
		SD	0.322	0.405
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	2.4	3.0
	Change from Baseline	n	273	280
		Mean	-1.15	-1.18
		SD	0.823	0.874
		Median	-1.00	-1.00
		Min.	-3.9	-3.9
		Max.	1.1	1.3

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Chest/Respiratory

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	Score	n	305	299
		Mean	0.18	0.15
		SD	0.365	0.315
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	1.9	1.9
	Change from Baseline	n	277	270
		Mean	-1.09	-1.11
		SD	0.812	0.804
		Median	-1.00	-1.00
		Min.	-3.4	-3.7
		Max.	0.7	1.3

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Gastrointestinal

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Score	n	451	460
		Mean	0.74	0.78
		SD	0.795	0.839
		Median	0.50	0.50
		Min.	0.0	0.0
		Max.	3.8	4.0
Day 7	Score	n	475	474
		Mean	0.44	0.29
		SD	0.611	0.536
		Median	0.25	0.00
		Min.	0.0	0.0
		Max.	3.8	4.0
	Change from Baseline	n	416	431
		Mean	-0.33	-0.50
		SD	0.692	0.769
		Median	-0.25	-0.25
		Min.	-3.5	-4.0
		Max.	1.5	2.0

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Gastrointestinal

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Day 14	Score	n	448	448
		Mean	0.20	0.14
		SD	0.432	0.347
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	3.3	2.8
	Change from Baseline	n	390	403
		Mean	-0.55	-0.63
		SD	0.721	0.757
		Median	-0.25	-0.50
		Min.	-3.5	-4.0
		Max.	1.5	1.5
Day 21	Score	n	415	440
		Mean	0.10	0.09
		SD	0.268	0.284
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	1.8	3.0
	Change from Baseline	n	360	398
		Mean	-0.65	-0.68
		SD	0.750	0.802
		Median	-0.50	-0.50
		Min.	-3.5	-4.0
		Max.	1.5	1.0

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Gastrointestinal

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Day 29	Score	n	320	319
		Mean	0.09	0.07
		SD	0.256	0.288
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	2.0	3.0
	Change from Baseline	n	294	294
		Mean	-0.67	-0.71
		SD	0.770	0.828
		Median	-0.50	-0.50
		Min.	-3.8	-4.0
		Max.	0.8	1.3
Week 8	Score	n	301	306
		Mean	0.07	0.06
		SD	0.224	0.256
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	2.0	2.8
	Change from Baseline	n	270	280
		Mean	-0.74	-0.74
		SD	0.771	0.828
		Median	-0.50	-0.50
		Min.	-3.0	-4.0
		Max.	0.8	1.5

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Gastrointestinal

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	Score	n	305	298
		Mean	0.09	0.07
		SD	0.286	0.306
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	2.8	3.0
	Change from Baseline	n	276	269
		Mean	-0.67	-0.63
		SD	0.732	0.821
		Median	-0.50	-0.50
		Min.	-3.3	-4.0
		Max.	1.8	2.8

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Body/Systemic

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Score	n	452	460
		Mean	1.45	1.47
		SD	0.865	0.912
		Median	1.36	1.36
		Min.	0.0	0.0
		Max.	3.9	4.0
Day 7	Score	n	475	474
		Mean	0.86	0.60
		SD	0.762	0.719
		Median	0.64	0.36
		Min.	0.0	0.0
		Max.	3.6	4.0
	Change from Baseline	n	417	431
		Mean	-0.63	-0.90
		SD	0.793	0.834
		Median	-0.55	-0.82
		Min.	-3.3	-3.6
		Max.	1.5	2.0

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Body/Systemic

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Day 14	Score	n	448	448
		Mean	0.45	0.32
		SD	0.571	0.522
		Median	0.27	0.09
		Min.	0.0	0.0
		Max.	2.8	3.5
	Change from Baseline	n	391	403
		Mean	-1.03	-1.16
		SD	0.848	0.878
		Median	-1.00	-1.18
		Min.	-3.6	-3.9
		Max.	1.1	1.3
Day 21	Score	n	415	440
		Mean	0.30	0.24
		SD	0.482	0.441
		Median	0.09	0.00
		Min.	0.0	0.0
		Max.	2.8	3.5
	Change from Baseline	n	361	398
		Mean	-1.19	-1.24
		SD	0.812	0.907
		Median	-1.18	-1.18
		Min.	-3.6	-3.9
		Max.	0.9	0.9

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Body/Systemic

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Day 29	Score	n	321	320
		Mean	0.24	0.16
		SD	0.404	0.369
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	2.3	3.0
	Change from Baseline	n	296	295
		Mean	-1.25	-1.31
		SD	0.813	0.892
		Median	-1.18	-1.18
		Min.	-3.8	-3.9
		Max.	0.5	0.5
Week 8	Score	n	302	306
		Mean	0.17	0.16
		SD	0.328	0.348
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	1.9	3.0
	Change from Baseline	n	272	280
		Mean	-1.38	-1.33
		SD	0.820	0.924
		Median	-1.32	-1.18
		Min.	-3.8	-3.9
		Max.	0.7	0.5

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Body/Systemic

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	Score	n	305	299
		Mean	0.20	0.16
		SD	0.350	0.315
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	2.0	2.5
	Change from Baseline	n	277	270
		Mean	-1.30	-1.27
		SD	0.836	0.846
		Median	-1.18	-1.23
		Min.	-3.8	-3.5
		Max.	1.3	0.7

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Sense

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Score	n	451	460
		Mean	0.51	0.52
		SD	0.462	0.474
		Median	0.50	0.50
		Min.	0.0	0.0
		Max.	1.0	1.0
Day 7	Score	n	475	474
		Mean	0.46	0.37
		SD	0.474	0.463
		Median	0.50	0.00
		Min.	0.0	0.0
		Max.	1.0	1.0
	Change from Baseline	n	416	431
		Mean	-0.07	-0.16
		SD	0.479	0.534
		Median	0.00	0.00
		Min.	-1.0	-1.0
		Max.	1.0	1.0

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Sense

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Day 14	Score	n	448	448
		Mean	0.28	0.22
		SD	0.430	0.400
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	1.0	1.0
	Change from Baseline	n	390	403
		Mean	-0.22	-0.30
		SD	0.530	0.552
		Median	0.00	0.00
		Min.	-1.0	-1.0
		Max.	1.0	1.0
Day 21	Score	n	415	440
		Mean	0.21	0.16
		SD	0.387	0.358
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	1.0	1.0
	Change from Baseline	n	360	398
		Mean	-0.31	-0.35
		SD	0.541	0.534
		Median	0.00	0.00
		Min.	-1.0	-1.0
		Max.	1.0	1.0

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Sense

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Day 29	Score	n	320	320
		Mean	0.13	0.11
		SD	0.311	0.297
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	1.0	1.0
	Change from Baseline	n	294	295
		Mean	-0.41	-0.43
		SD	0.526	0.525
		Median	-0.50	-0.50
		Min.	-1.0	-1.0
		Max.	1.0	1.0
Week 8	Score	n	302	306
		Mean	0.07	0.08
		SD	0.235	0.267
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	1.0	1.0
	Change from Baseline	n	271	280
		Mean	-0.47	-0.46
		SD	0.490	0.512
		Median	-0.50	-0.50
		Min.	-1.0	-1.0
		Max.	1.0	1.0

Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Table 4.101
Summary of Absolute and Change from Baseline of COVID-19-Related Illness as Measured by FLU-PRO Plus

Domain: Sense

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	Score	n	305	299
		Mean	0.07	0.06
		SD	0.238	0.234
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	1.0	1.0
	Change from Baseline	n	276	270
		Mean	-0.43	-0.42
		SD	0.487	0.514
		Median	-0.50	0.00
		Min.	-1.0	-1.0
		Max.	1.0	1.0

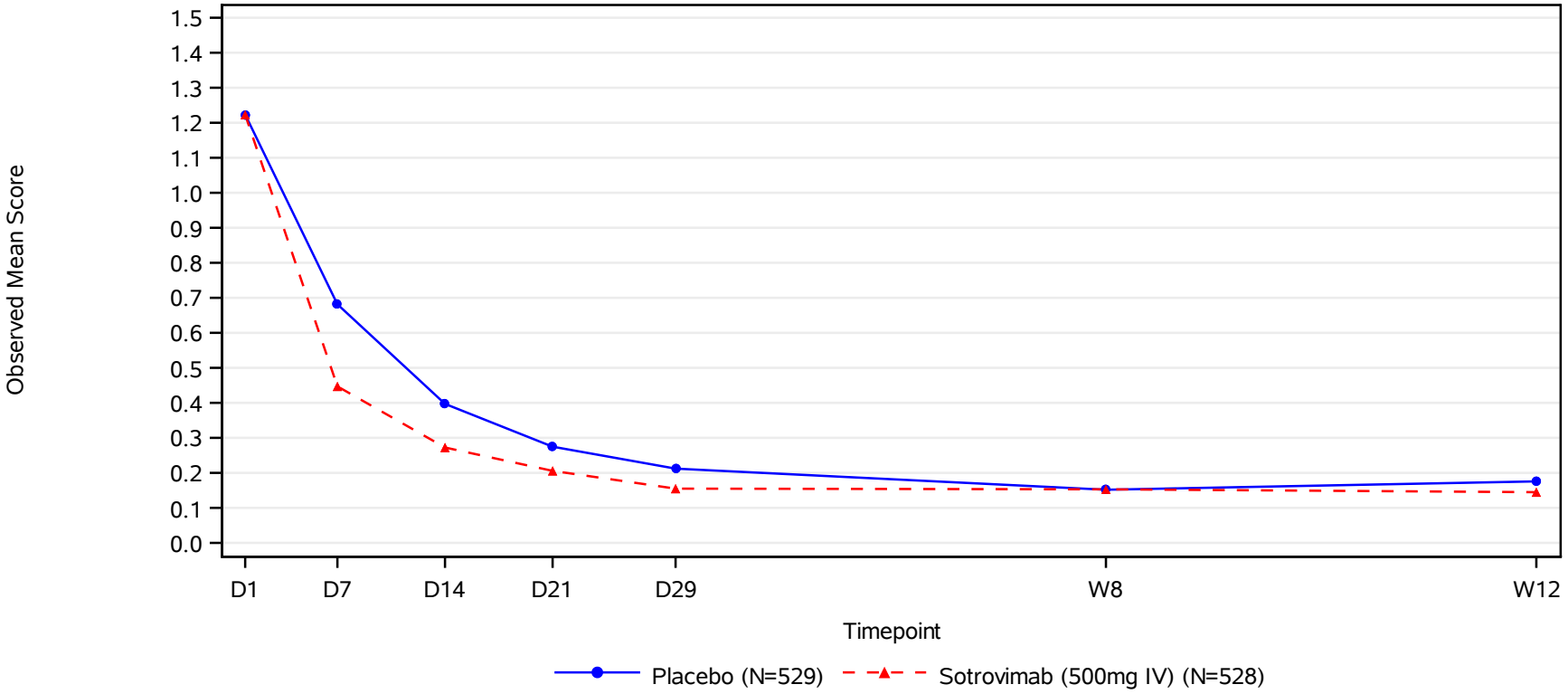
Note: Missing domain/total score at Days 7, 14 and 21 were imputed using an LOCF approach.

PPD

Protocol: 214367
Population: Intent-to-Treat

Figure 34.1
Plot of Observed Mean FLU-PRO Plus Score by Timepoint

Domain: Total Score



Placebo (n)	451	312	301	263	320	301	305
Sotrovimab (500mg IV) (n)	459	309	279	277	319	306	298

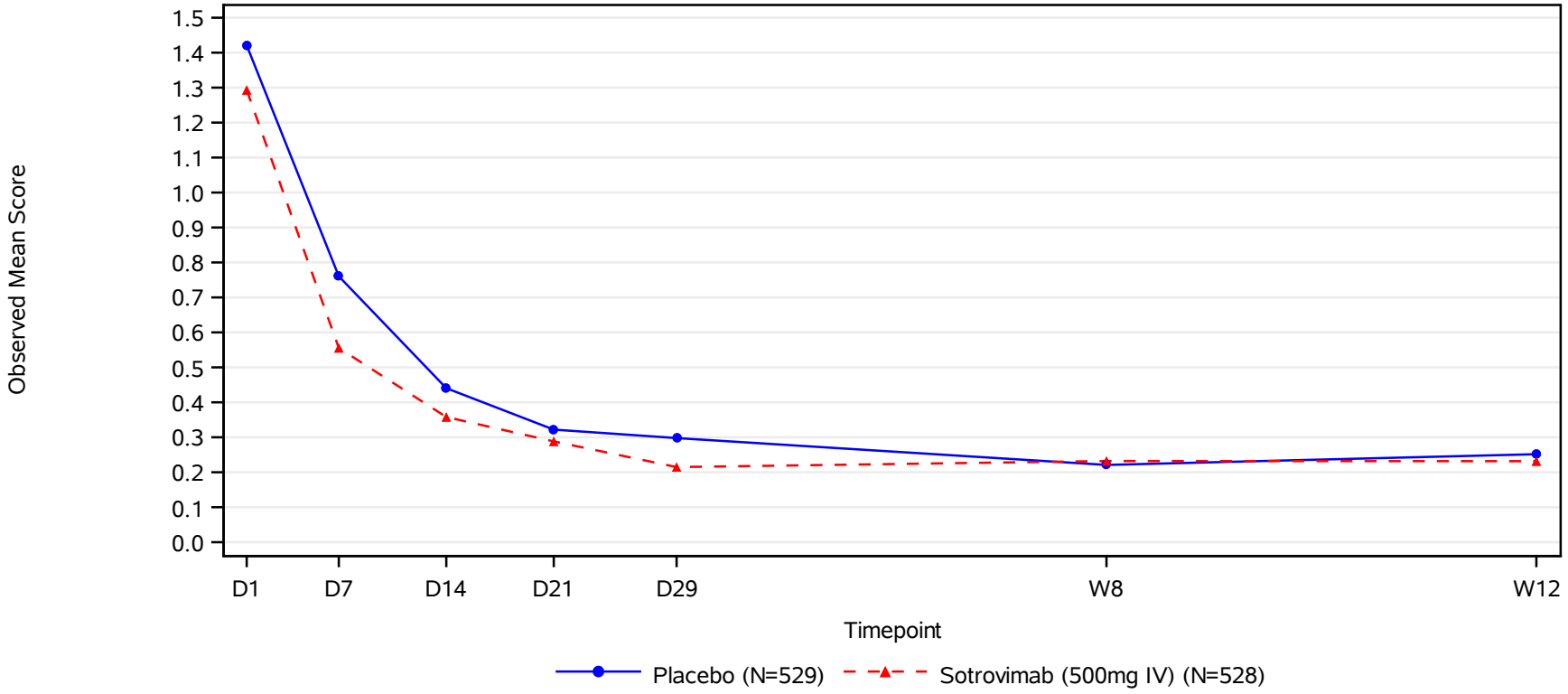
Note: D29, W8 and W12 includes all questionnaires from the Day 29, Week 8 and Week 12 visits (respectively), regardless of study day completed.

PPD

Protocol: 214367
Population: Intent-to-Treat

Figure 34.1
Plot of Observed Mean FLU-PRO Plus Score by Timepoint

Domain: Nose



Placebo (n)	453	314	301	264	321	301	305
Sotrovimab (500mg IV) (n)	459	311	280	277	320	307	299

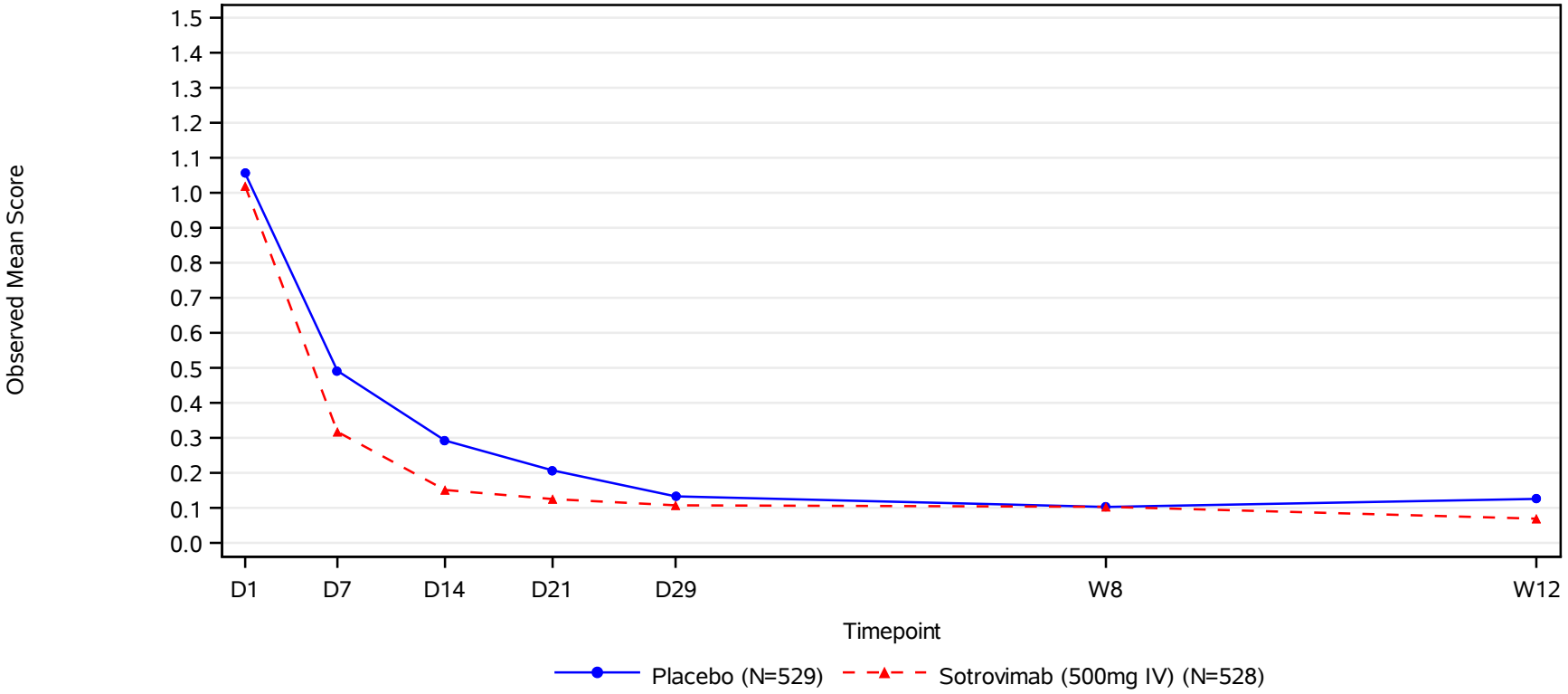
Note: D29, W8 and W12 includes all questionnaires from the Day 29, Week 8 and Week 12 visits (respectively), regardless of study day completed.

PPD

Protocol: 214367
Population: Intent-to-Treat

Figure 34.1
Plot of Observed Mean FLU-PRO Plus Score by Timepoint

Domain: Throat



Placebo (n)	453	314	301	264	321	302	305
Sotrovimab (500mg IV) (n)	460	311	280	277	320	307	299

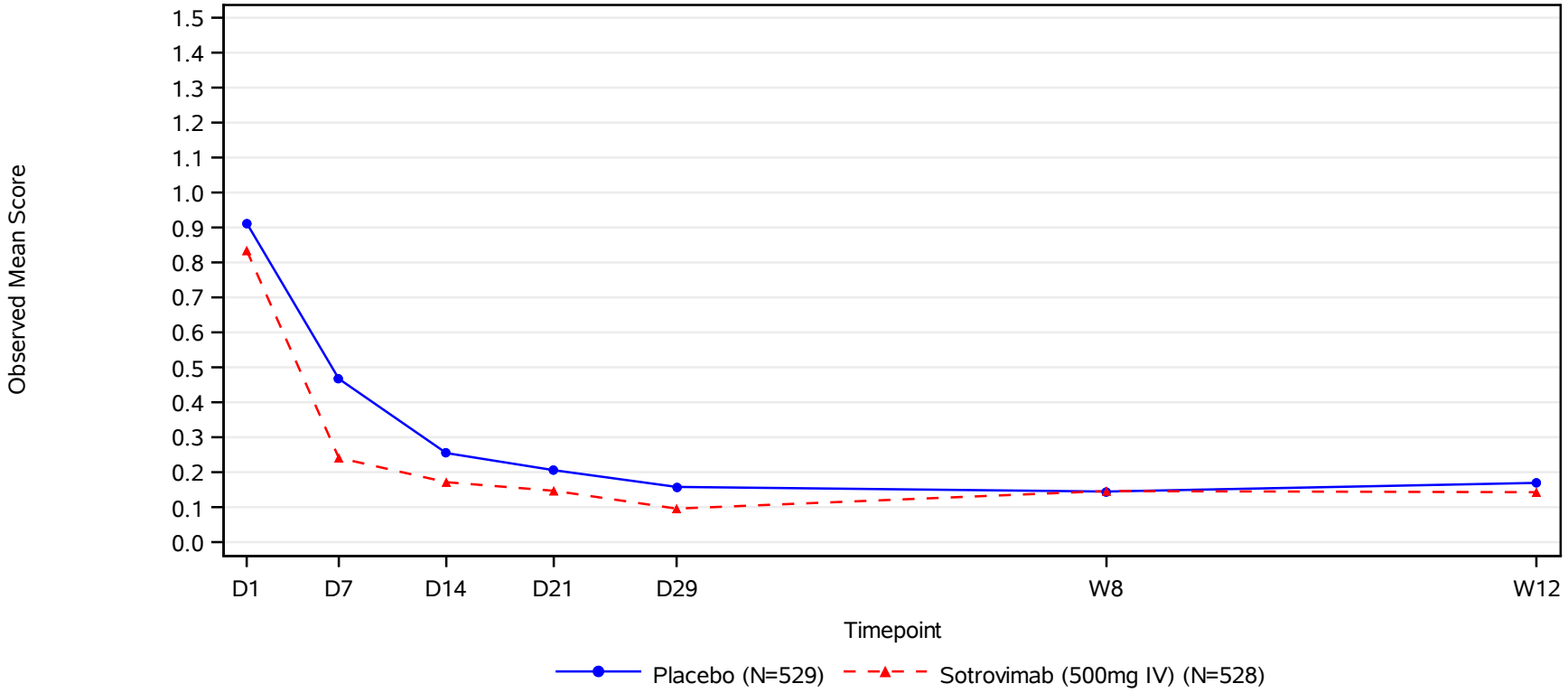
Note: D29, W8 and W12 includes all questionnaires from the Day 29, Week 8 and Week 12 visits (respectively), regardless of study day completed.

PPD

Protocol: 214367
Population: Intent-to-Treat

Figure 34.1
Plot of Observed Mean FLU-PRO Plus Score by Timepoint

Domain: Eyes



Placebo (n)	453	314	301	264	321	302	305
Sotrovimab (500mg IV) (n)	460	310	280	277	320	307	299

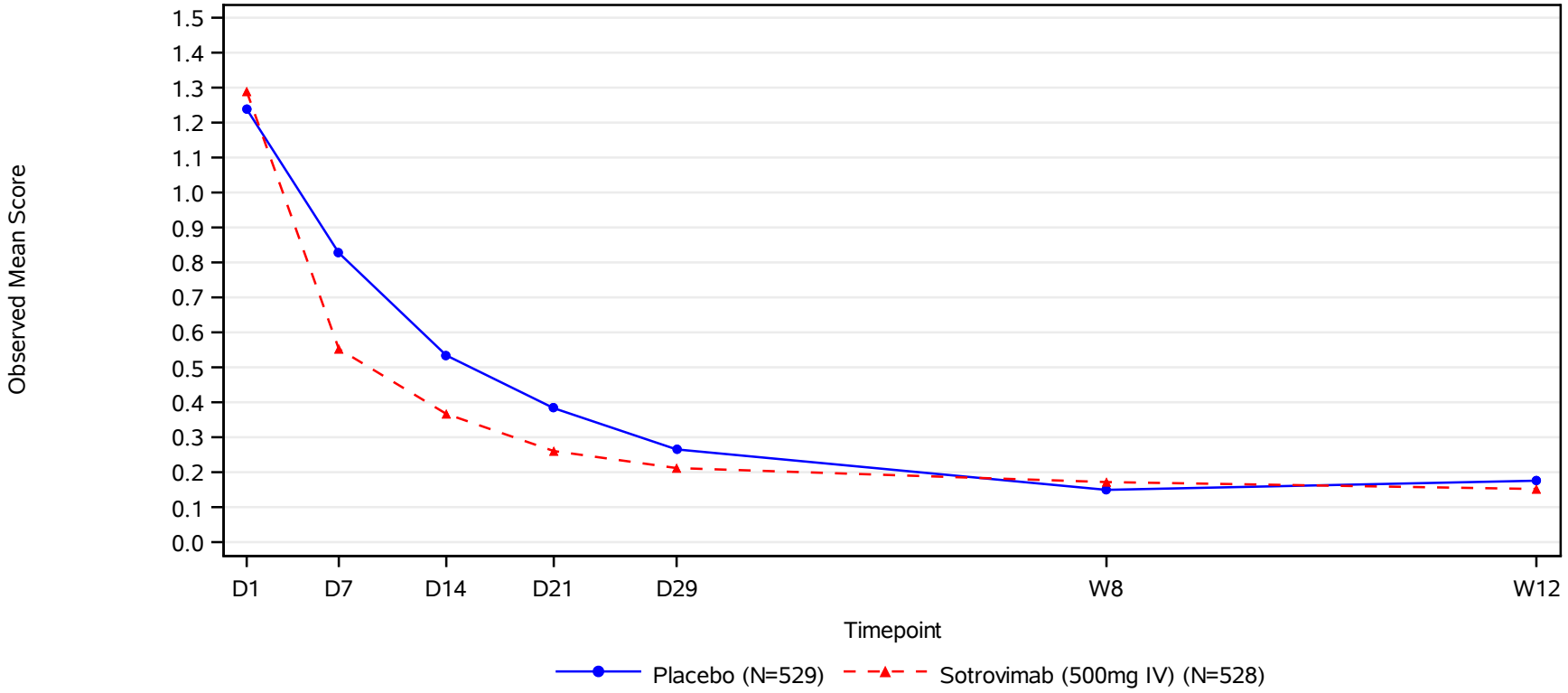
Note: D29, W8 and W12 includes all questionnaires from the Day 29, Week 8 and Week 12 visits (respectively), regardless of study day completed.

PPD

Protocol: 214367
Population: Intent-to-Treat

Figure 34.1
Plot of Observed Mean FLU-PRO Plus Score by Timepoint

Domain: Chest/Respiratory



Placebo (n)	453	314	301	264	321	302	305
Sotrovimab (500mg IV) (n)	460	311	280	277	320	307	299

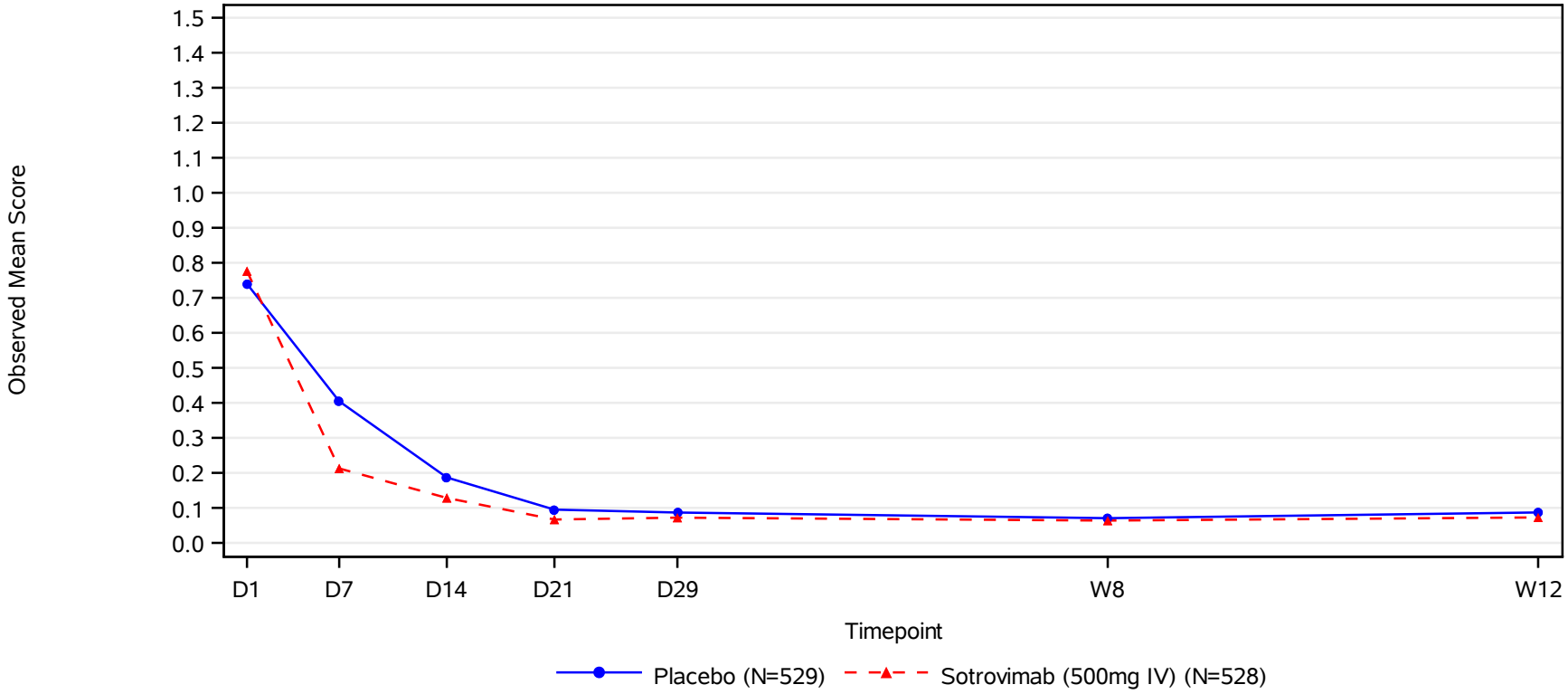
Note: D29, W8 and W12 includes all questionnaires from the Day 29, Week 8 and Week 12 visits (respectively), regardless of study day completed.

PPD

Protocol: 214367
Population: Intent-to-Treat

Figure 34.1
Plot of Observed Mean FLU-PRO Plus Score by Timepoint

Domain: Gastrointestinal



Placebo (n)	451	312	301	263	320	301	305
Sotrovimab (500mg IV) (n)	460	310	279	277	319	306	298

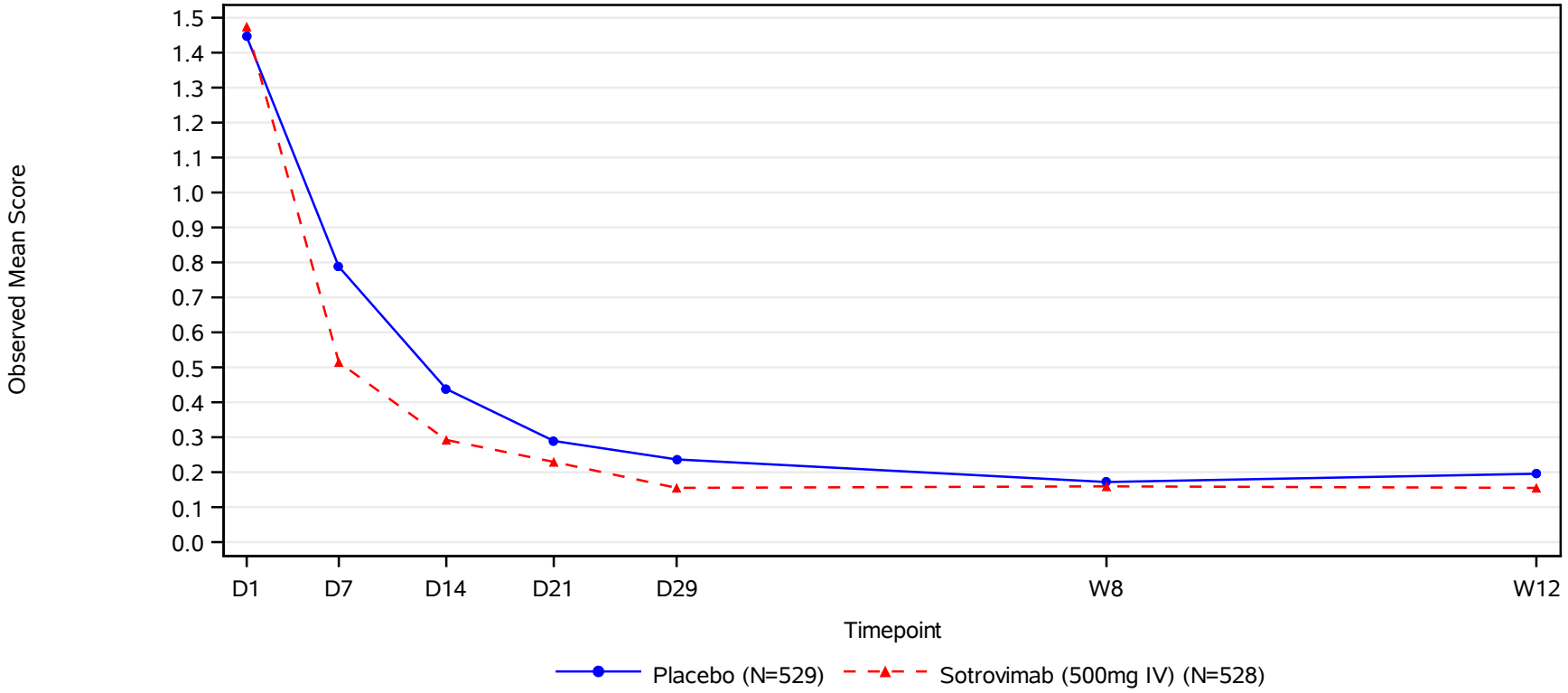
Note: D29, W8 and W12 includes all questionnaires from the Day 29, Week 8 and Week 12 visits (respectively), regardless of study day completed.

PPD

Protocol: 214367
Population: Intent-to-Treat

Figure 34.1
Plot of Observed Mean FLU-PRO Plus Score by Timepoint

Domain: Body/Systemic



Placebo (n)	452	312	301	263	321	302	305
Sotrovimab (500mg IV) (n)	460	310	280	277	320	306	299

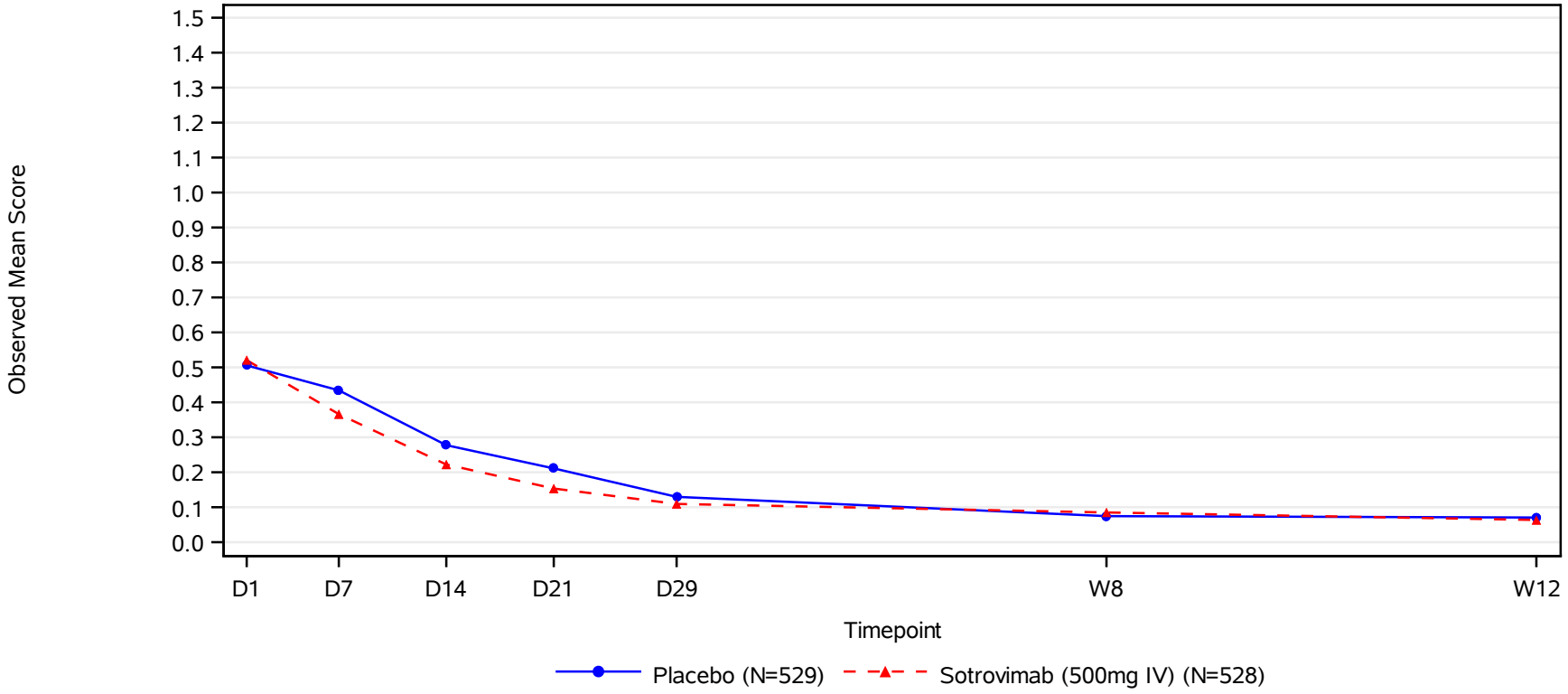
Note: D29, W8 and W12 includes all questionnaires from the Day 29, Week 8 and Week 12 visits (respectively), regardless of study day completed.

PPD

Protocol: 214367
Population: Intent-to-Treat

Figure 34.1
Plot of Observed Mean FLU-PRO Plus Score by Timepoint

Domain: Sense



Placebo (n)	451	312	301	263	320	302	305
Sotrovimab (500mg IV) (n)	460	310	279	277	320	306	299

Note: D29, W8 and W12 includes all questionnaires from the Day 29, Week 8 and Week 12 visits (respectively), regardless of study day completed.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	399	399
		Mean	56.27	57.27
		SD	33.563	33.161
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 15	SF-12 Score	n	232	248
		Mean	72.70	77.24
		SD	30.792	29.484
		Median	75.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	207	215
		Mean	13.65	18.75
		SD	37.178	37.737
		Median	0.00	25.00
		Min.	-100.0	-75.0
		Max.	100.0	100.0

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	79.18	80.91
		SD	26.964	28.936
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	215	209
		Mean	19.83	23.33
		SD	35.964	37.861
		Median	8.95	25.00
		Min.	-75.0	-100.0
		Max.	100.0	100.0

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	399	399
		Mean	43.29	43.61
		SD	10.566	10.439
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 15	SF-12 Score	n	232	248
		Mean	48.47	49.90
		SD	9.693	9.282
		Median	49.19	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	207	215
		Mean	4.30	5.90
		SD	11.704	11.880
		Median	0.00	7.87
		Min.	-31.5	-23.6
		Max.	31.5	31.5

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	50.51	51.05
		SD	8.488	9.109
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	215	209
		Mean	6.24	7.34
		SD	11.322	11.919
		Median	2.81	7.87
		Min.	-23.6	-31.5
		Max.	31.5	31.5

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	398	399
		Mean	50.44	52.51
		SD	27.543	28.658
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 15	SF-12 Score	n	232	248
		Mean	68.97	75.05
		SD	28.584	26.534
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	207	215
		Mean	17.75	22.97
		SD	31.623	33.240
		Median	12.50	25.00
		Min.	-75.0	-100.0
		Max.	100.0	100.0

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	76.70	80.55
		SD	24.831	25.738
		Median	75.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	215	209
		Mean	26.57	28.89
		SD	30.302	32.692
		Median	25.00	25.00
		Min.	-50.0	-62.5
		Max.	100.0	100.0

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	398	399
		Mean	40.69	41.38
		SD	9.324	9.701
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 15	SF-12 Score	n	232	248
		Mean	46.96	49.02
		SD	9.676	8.981
		Median	49.00	49.00
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	207	215
		Mean	6.01	7.77
		SD	10.705	11.252
		Median	4.23	8.46
		Min.	-25.4	-33.9
		Max.	33.9	33.9

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	49.58	50.88
		SD	8.405	8.712
		Median	49.00	57.46
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	215	209
		Mean	8.99	9.78
		SD	10.257	11.067
		Median	8.46	8.46
		Min.	-16.9	-21.2
		Max.	33.9	33.9

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	397	399
		Mean	62.22	60.78
		SD	29.280	30.071
		Median	75.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 15	SF-12 Score	n	232	248
		Mean	79.53	85.38
		SD	25.609	23.064
		Median	87.50	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	207	215
		Mean	16.43	25.23
		SD	32.148	32.153
		Median	25.00	25.00
		Min.	-100.0	-100.0
		Max.	100.0	100.0

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	85.70	88.69
		SD	22.692	21.633
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	215	209
		Mean	23.37	27.51
		SD	30.142	31.341
		Median	25.00	25.00
		Min.	-50.0	-75.0
		Max.	100.0	100.0

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	397	399
		Mean	44.10	43.58
		SD	10.563	10.848
		Median	48.71	39.69
		Min.	21.7	21.7
		Max.	57.7	57.7
Day 15	SF-12 Score	n	232	248
		Mean	50.34	52.46
		SD	9.239	8.321
		Median	53.22	57.73
		Min.	21.7	21.7
		Max.	57.7	57.7
	Change from Baseline	n	207	215
		Mean	5.93	9.10
		SD	11.598	11.600
		Median	9.02	9.02
		Min.	-36.1	-36.1
		Max.	36.1	36.1

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	52.57	53.65
		SD	8.187	7.805
		Median	57.73	57.73
		Min.	21.7	21.7
		Max.	57.7	57.7
	Change from Baseline	n	215	209
		Mean	8.43	9.93
		SD	10.875	11.307
		Median	9.02	9.02
		Min.	-18.0	-27.1
		Max.	36.1	36.1

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	399	399
		Mean	55.83	53.98
		SD	28.281	29.274
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 15	SF-12 Score	n	232	247
		Mean	66.94	68.28
		SD	23.213	19.443
		Median	60.00	60.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	207	214
		Mean	9.64	12.38
		SD	25.241	28.964
		Median	0.00	0.00
		Min.	-75.0	-75.0
		Max.	75.0	100.0

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	70.88	68.65
		SD	20.471	20.360
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	215	209
		Mean	13.09	13.54
		SD	25.506	31.591
		Median	0.00	0.00
		Min.	-60.0	-100.0
		Max.	85.0	85.0

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	399	399
		Mean	46.09	45.36
		SD	11.243	11.637
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 15	SF-12 Score	n	232	247
		Mean	50.51	51.04
		SD	9.229	7.730
		Median	47.75	47.75
		Min.	23.9	33.8
		Max.	63.7	63.7
	Change from Baseline	n	207	214
		Mean	3.83	4.92
		SD	10.035	11.515
		Median	0.00	0.00
		Min.	-29.8	-29.8
		Max.	29.8	39.8

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	52.08	51.19
		SD	8.139	8.095
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
	Change from Baseline	n	215	209
		Mean	5.21	5.38
		SD	10.140	12.559
		Median	0.00	0.00
		Min.	-23.8	-39.8
		Max.	33.8	33.8

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	398	399
		Mean	36.43	36.47
		SD	27.909	27.939
		Median	25.00	25.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 15	SF-12 Score	n	232	248
		Mean	52.16	56.05
		SD	34.040	32.966
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	207	215
		Mean	20.41	23.26
		SD	32.634	35.271
		Median	25.00	25.00
		Min.	-50.0	-100.0
		Max.	100.0	100.0

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	240
		Mean	60.02	66.46
		SD	31.627	32.503
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	215	209
		Mean	25.23	28.59
		SD	31.879	38.904
		Median	25.00	25.00
		Min.	-50.0	-100.0
		Max.	100.0	100.0

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	398	399
		Mean	43.73	43.74
		SD	10.982	10.994
		Median	39.23	39.23
		Min.	29.4	29.4
		Max.	68.7	68.7
Day 15	SF-12 Score	n	232	248
		Mean	49.91	51.45
		SD	13.394	12.971
		Median	49.07	49.07
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	207	215
		Mean	8.03	9.15
		SD	12.841	13.878
		Median	9.83	9.84
		Min.	-19.7	-39.3
		Max.	39.3	39.3

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	240
		Mean	53.01	55.54
		SD	12.444	12.789
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	215	209
		Mean	9.93	11.25
		SD	12.544	15.308
		Median	9.84	9.84
		Min.	-19.7	-39.3
		Max.	39.3	39.3

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	398	399
		Mean	46.98	46.74
		SD	35.934	35.955
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 15	SF-12 Score	n	232	247
		Mean	69.50	78.74
		SD	34.180	31.049
		Median	75.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	207	214
		Mean	22.83	32.36
		SD	42.109	43.350
		Median	25.00	25.00
		Min.	-75.0	-100.0
		Max.	100.0	100.0

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	80.74	86.00
		SD	26.675	25.484
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	215	209
		Mean	33.14	39.35
		SD	39.388	40.397
		Median	25.00	50.00
		Min.	-75.0	-75.0
		Max.	100.0	100.0

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	398	399
		Mean	38.04	37.95
		SD	12.785	12.793
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 15	SF-12 Score	n	232	247
		Mean	46.05	49.34
		SD	12.161	11.047
		Median	48.01	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	207	214
		Mean	8.12	11.51
		SD	14.982	15.424
		Median	8.89	8.90
		Min.	-26.7	-35.6
		Max.	35.6	35.6

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	50.05	51.92
		SD	9.490	9.066
		Median	56.90	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	215	209
		Mean	11.79	14.00
		SD	14.014	14.373
		Median	8.90	17.79
		Min.	-26.7	-26.7
		Max.	35.6	35.6

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	398	399
		Mean	64.86	66.95
		SD	27.950	29.076
		Median	62.50	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 15	SF-12 Score	n	232	248
		Mean	80.93	83.22
		SD	23.606	23.539
		Median	100.00	100.00
		Min.	12.5	0.0
		Max.	100.0	100.0
	Change from Baseline	n	207	215
		Mean	13.83	15.99
		SD	27.564	28.071
		Median	0.00	12.50
		Min.	-75.0	-75.0
		Max.	100.0	100.0

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	83.90	87.86
		SD	23.237	22.314
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	215	209
		Mean	17.91	21.23
		SD	28.169	31.442
		Median	12.50	12.50
		Min.	-75.0	-62.5
		Max.	87.5	100.0

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	398	399
		Mean	41.67	42.54
		SD	11.623	12.091
		Median	40.69	45.89
		Min.	14.7	14.7
		Max.	56.3	56.3
Day 15	SF-12 Score	n	232	248
		Mean	48.35	49.30
		SD	9.816	9.787
		Median	56.28	56.28
		Min.	19.9	14.7
		Max.	56.3	56.3
	Change from Baseline	n	207	215
		Mean	5.75	6.65
		SD	11.462	11.673
		Median	0.00	5.19
		Min.	-31.2	-31.2
		Max.	41.6	41.6

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Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	49.59	51.23
		SD	9.662	9.278
		Median	56.28	56.28
		Min.	14.7	14.7
		Max.	56.3	56.3
	Change from Baseline	n	215	209
		Mean	7.45	8.83
		SD	11.713	13.074
		Median	5.20	5.20
		Min.	-31.2	-26.0
		Max.	36.4	41.6

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	398	399
		Mean	58.42	59.18
		SD	22.511	23.792
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 15	SF-12 Score	n	232	248
		Mean	72.74	73.99
		SD	23.442	22.185
		Median	75.00	75.00
		Min.	0.0	12.5
		Max.	100.0	100.0
	Change from Baseline	n	207	215
		Mean	14.61	15.23
		SD	26.114	28.829
		Median	12.50	12.50
		Min.	-50.0	-50.0
		Max.	100.0	100.0

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Population: Intent-to-Treat Data as of 27APR2021

Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	74.66	78.27
		SD	22.108	21.356
		Median	75.00	87.50
		Min.	12.5	12.5
		Max.	100.0	100.0
	Change from Baseline	n	215	209
		Mean	16.28	20.81
		SD	25.993	29.628
		Median	12.50	12.50
		Min.	-37.5	-50.0
		Max.	75.0	100.0

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	398	399
		Mean	45.13	45.48
		SD	10.331	10.918
		Median	41.26	41.26
		Min.	18.3	18.3
		Max.	64.2	64.2
Day 15	SF-12 Score	n	232	248
		Mean	51.70	52.27
		SD	10.758	10.182
		Median	52.74	52.74
		Min.	18.3	24.1
		Max.	64.2	64.2
	Change from Baseline	n	207	215
		Mean	6.71	6.99
		SD	11.985	13.231
		Median	5.73	5.74
		Min.	-23.0	-23.0
		Max.	45.9	45.9

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	52.58	54.24
		SD	10.146	9.801
		Median	52.74	58.47
		Min.	24.1	24.1
		Max.	64.2	64.2
	Change from Baseline	n	215	209
		Mean	7.47	9.55
		SD	11.929	13.597
		Median	5.74	5.74
		Min.	-17.2	-23.0
		Max.	34.4	45.9

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	398	399
		Mean	43.61	43.41
		SD	9.118	8.912
		Median	43.93	43.91
		Min.	17.4	20.2
		Max.	62.6	64.6
Day 15	SF-12 Score	n	232	248
		Mean	48.49	50.32
		SD	8.828	7.675
		Median	50.41	52.52
		Min.	20.6	24.2
		Max.	69.3	69.8
	Change from Baseline	n	207	215
		Mean	4.36	6.70
		SD	9.438	9.623
		Median	4.09	6.85
		Min.	-19.7	-19.4
		Max.	37.6	30.8

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	51.00	51.18
		SD	7.352	7.962
		Median	52.32	53.65
		Min.	22.7	23.5
		Max.	65.3	69.4
	Change from Baseline	n	215	209
		Mean	6.90	7.46
		SD	8.860	9.348
		Median	5.67	7.67
		Min.	-13.3	-19.7
		Max.	35.6	30.0

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	398	399
		Mean	42.65	43.08
		SD	10.032	10.357
		Median	42.05	41.98
		Min.	13.8	11.0
		Max.	73.0	69.3
Day 15	SF-12 Score	n	232	248
		Mean	49.71	50.85
		SD	9.852	9.980
		Median	51.32	51.55
		Min.	24.1	13.4
		Max.	65.9	73.8
	Change from Baseline	n	207	215
		Mean	7.46	8.22
		SD	10.831	11.913
		Median	6.23	7.81
		Min.	-16.1	-29.1
		Max.	46.3	43.7

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	51.45	53.67
		SD	9.857	8.910
		Median	53.20	55.60
		Min.	16.0	20.4
		Max.	65.6	66.8
	Change from Baseline	n	215	209
		Mean	8.92	10.94
		SD	11.129	12.445
		Median	7.31	10.98
		Min.	-18.4	-20.6
		Max.	45.3	43.7

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	397	399
		Mean	0.643	0.642
		SD	0.1223	0.1305
		Median	0.619	0.618
		Min.	0.35	0.35
		Max.	1.00	1.00
Day 15	SF-12 Score	n	232	245
		Mean	0.751	0.787
		SD	0.1464	0.1459
		Median	0.736	0.797
		Min.	0.38	0.37
		Max.	1.00	1.00
	Change from Baseline	n	207	212
		Mean	0.108	0.149
		SD	0.1577	0.1677
		Median	0.089	0.131
		Min.	-0.31	-0.30
		Max.	0.53	0.66

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	240
		Mean	0.792	0.836
		SD	0.1483	0.1504
		Median	0.796	0.860
		Min.	0.41	0.43
		Max.	1.00	1.00
	Change from Baseline	n	215	209
		Mean	0.152	0.194
		SD	0.1595	0.1842
		Median	0.124	0.200
		Min.	-0.26	-0.31
		Max.	0.52	0.66

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	398	399
		Mean	48.71	49.56
		SD	26.351	27.814
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 15	SF-12 Score	n	232	248
		Mean	69.48	76.39
		SD	28.221	25.658
		Median	75.00	87.50
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	207	215
		Mean	20.71	27.35
		SD	29.181	31.123
		Median	18.75	25.00
		Min.	-75.0	-62.5
		Max.	100.0	100.0

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	78.02	82.47
		SD	23.445	23.710
		Median	87.50	93.75
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	215	209
		Mean	29.51	33.67
		SD	28.292	31.026
		Median	25.00	37.50
		Min.	-56.3	-56.3
		Max.	100.0	100.0

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	398	399
		Mean	38.73	39.03
		SD	9.467	9.993
		Median	39.19	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 15	SF-12 Score	n	232	248
		Mean	46.19	48.67
		SD	10.140	9.220
		Median	48.17	52.66
		Min.	21.2	21.2
		Max.	57.2	57.2
	Change from Baseline	n	207	215
		Mean	7.44	9.83
		SD	10.485	11.182
		Median	6.74	8.98
		Min.	-26.9	-22.5
		Max.	35.9	35.9

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	49.26	50.86
		SD	8.424	8.520
		Median	52.66	54.91
		Min.	21.2	21.2
		Max.	57.2	57.2
	Change from Baseline	n	215	209
		Mean	10.60	12.10
		SD	10.165	11.147
		Median	8.99	13.47
		Min.	-20.2	-20.2
		Max.	35.9	35.9

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	398	399
		Mean	40.80	40.93
		SD	24.198	24.566
		Median	43.75	43.75
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 15	SF-12 Score	n	232	248
		Mean	60.24	63.99
		SD	28.149	26.195
		Median	62.50	68.75
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	207	215
		Mean	22.89	25.09
		SD	26.866	27.639
		Median	18.75	25.00
		Min.	-50.0	-37.5
		Max.	93.8	87.5

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	67.05	72.42
		SD	25.360	24.986
		Median	68.75	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	215	209
		Mean	27.88	32.09
		SD	25.647	28.786
		Median	25.00	31.25
		Min.	-50.0	-50.0
		Max.	93.8	100.0

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	398	399
		Mean	42.28	42.35
		SD	11.503	11.678
		Median	43.69	43.69
		Min.	22.9	22.9
		Max.	70.4	70.4
Day 15	SF-12 Score	n	232	248
		Mean	51.52	53.31
		SD	13.379	12.450
		Median	52.60	55.57
		Min.	22.9	22.9
		Max.	70.4	70.4
	Change from Baseline	n	207	215
		Mean	10.88	11.92
		SD	12.770	13.137
		Median	8.92	11.88
		Min.	-23.8	-17.8
		Max.	44.6	41.6

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Table 4.15
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	SF-12 Score	n	257	241
		Mean	54.76	57.31
		SD	12.053	11.875
		Median	55.57	58.54
		Min.	22.9	22.9
		Max.	70.4	70.4
	Change from Baseline	n	215	209
		Mean	13.25	15.25
		SD	12.190	13.682
		Median	11.89	14.86
		Min.	-23.8	-23.8
		Max.	44.6	47.5

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Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Physical Functioning (0-100 score)
Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	207	215
LS Mean (SE)	73.68 (1.938)	77.46 (1.901)
95% C.I.	(69.87, 77.49)	(73.72, 81.19)
LS Mean Change from Baseline (SE)	14.35 (1.938)	18.13 (1.901)
95% C.I.	(10.54, 18.16)	(14.39, 21.86)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.78 (2.715)
95% C.I.		(-1.56, 9.11)
p-value		0.165
Corrected Hedge’s g (SE) [3]		0.14 (0.097)
95% C.I.		(-0.06, 0.33)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Physical Functioning (0-100 score)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	215	209
LS Mean (SE)	80.41 (1.777)	81.33 (1.785)
95% C.I.	(76.92, 83.90)	(77.82, 84.84)
LS Mean Change from Baseline (SE)	21.08 (1.777)	22.00 (1.785)
95% C.I.	(17.59, 24.57)	(18.49, 25.51)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.92 (2.520)
95% C.I.		(-4.03, 5.87)
p-value		0.715
Corrected Hedge’s g (SE) [3]		0.04 (0.097)
95% C.I.		(-0.15, 0.23)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Role Physical (0-100 score)
Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	207	215
LS Mean (SE)	69.55 (1.764)	74.62 (1.730)
95% C.I.	(66.08, 73.01)	(71.22, 78.02)
LS Mean Change from Baseline (SE)	18.18 (1.764)	23.25 (1.730)
95% C.I.	(14.72, 21.65)	(19.85, 26.66)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		5.07 (2.471)
95% C.I.		(0.22, 9.93)
p-value		0.041
Corrected Hedge’s g (SE) [3]		0.20 (0.098)
95% C.I.		(0.01, 0.39)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Role Physical (0-100 score)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	215	209
LS Mean (SE)	77.53 (1.615)	80.17 (1.623)
95% C.I.	(74.35, 80.70)	(76.98, 83.36)
LS Mean Change from Baseline (SE)	26.16 (1.615)	28.80 (1.623)
95% C.I.	(22.98, 29.33)	(25.61, 31.99)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.64 (2.290)
95% C.I.		(-1.86, 7.14)
p-value		0.249
Corrected Hedge’s g (SE) [3]		0.11 (0.097)
95% C.I.		(-0.08, 0.30)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Bodily Pain (0-100 score)
Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	207	215
LS Mean (SE)	79.58 (1.609)	86.28 (1.578)
95% C.I.	(76.41, 82.74)	(83.18, 89.38)
LS Mean Change from Baseline (SE)	17.53 (1.609)	24.24 (1.578)
95% C.I.	(14.37, 20.69)	(21.14, 27.34)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		6.71 (2.255)
95% C.I.		(2.27, 11.14)
p-value		0.003
Corrected Hedge’s g (SE) [3]		0.29 (0.098)
95% C.I.		(0.10, 0.48)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Bodily Pain (0-100 score)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	215	209
LS Mean (SE)	86.59 (1.438)	88.60 (1.453)
95% C.I.	(83.76, 89.42)	(85.75, 91.46)
LS Mean Change from Baseline (SE)	24.55 (1.438)	26.56 (1.453)
95% C.I.	(21.72, 27.38)	(23.70, 29.41)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.01 (2.045)
95% C.I.		(-2.01, 6.03)
p-value		0.326
Corrected Hedge’s g (SE) [3]		0.10 (0.097)
95% C.I.		(-0.10, 0.29)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: General Health (0-100 score)
Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	207	214
LS Mean (SE)	67.32 (1.345)	68.20 (1.322)
95% C.I.	(64.68, 69.97)	(65.60, 70.79)
LS Mean Change from Baseline (SE)	10.80 (1.345)	11.67 (1.322)
95% C.I.	(8.15, 13.44)	(9.07, 14.27)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.87 (1.887)
95% C.I.		(-2.83, 4.58)
p-value		0.644
Corrected Hedge’s g (SE) [3]		0.05 (0.097)
95% C.I.		(-0.15, 0.24)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: General Health (0-100 score)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	215	209
LS Mean (SE)	71.01 (1.310)	68.45 (1.318)
95% C.I.	(68.44, 73.59)	(65.86, 71.04)
LS Mean Change from Baseline (SE)	14.49 (1.310)	11.92 (1.318)
95% C.I.	(11.91, 17.06)	(9.33, 14.51)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.56 (1.861)
95% C.I.		(-6.22, 1.09)
p-value		0.169
Corrected Hedge’s g (SE) [3]		-0.13 (0.097)
95% C.I.		(-0.32, 0.06)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Vitality (0-100 score)
Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	207	215
LS Mean (SE)	54.65 (2.096)	57.55 (2.056)
95% C.I.	(50.53, 58.76)	(53.51, 61.59)
LS Mean Change from Baseline (SE)	19.86 (2.096)	22.76 (2.056)
95% C.I.	(15.74, 23.98)	(18.72, 26.80)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.91 (2.933)
95% C.I.		(-2.86, 8.67)
p-value		0.322
Corrected Hedge’s g (SE) [3]		0.10 (0.097)
95% C.I.		(-0.09, 0.29)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Vitality (0-100 score)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	215	209
LS Mean (SE)	59.84 (2.044)	64.46 (2.057)
95% C.I.	(55.82, 63.85)	(60.41, 68.50)
LS Mean Change from Baseline (SE)	25.05 (2.044)	29.67 (2.057)
95% C.I.	(21.03, 29.06)	(25.63, 33.71)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.62 (2.899)
95% C.I.		(-1.08, 10.32)
p-value		0.112
Corrected Hedge’s g (SE) [3]		0.15 (0.097)
95% C.I.		(-0.04, 0.35)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Social Functioning (0-100 score)
Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	265
n [2]	207	214
LS Mean (SE)	69.41 (2.198)	78.22 (2.161)
95% C.I.	(65.09, 73.73)	(73.97, 82.47)
LS Mean Change from Baseline (SE)	22.97 (2.198)	31.78 (2.161)
95% C.I.	(18.65, 27.29)	(27.53, 36.03)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		8.81 (3.083)
95% C.I.		(2.75, 14.87)
p-value		0.004
Corrected Hedge’s g (SE) [3]		0.28 (0.098)
95% C.I.		(0.09, 0.47)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Social Functioning (0-100 score)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	265
n [2]	215	209
LS Mean (SE)	80.94 (1.752)	86.01 (1.770)
95% C.I.	(77.50, 84.39)	(82.53, 89.49)
LS Mean Change from Baseline (SE)	34.50 (1.752)	39.57 (1.770)
95% C.I.	(31.06, 37.94)	(36.09, 43.05)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		5.07 (2.490)
95% C.I.		(0.17, 9.96)
p-value		0.043
Corrected Hedge’s g (SE) [3]		0.20 (0.097)
95% C.I.		(0.01, 0.39)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Role Emotional (0-100 score)
Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	207	215
LS Mean (SE)	80.42 (1.454)	83.58 (1.427)
95% C.I.	(77.56, 83.28)	(80.77, 86.38)
LS Mean Change from Baseline (SE)	13.45 (1.454)	16.62 (1.427)
95% C.I.	(10.60, 16.31)	(13.81, 19.42)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.16 (2.037)
95% C.I.		(-0.84, 7.16)
p-value		0.122
Corrected Hedge’s g (SE) [3]		0.15 (0.098)
95% C.I.		(-0.04, 0.34)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Role Emotional (0-100 score)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	215	209
LS Mean (SE)	84.76 (1.466)	87.72 (1.477)
95% C.I.	(81.88, 87.64)	(84.82, 90.63)
LS Mean Change from Baseline (SE)	17.79 (1.466)	20.76 (1.477)
95% C.I.	(14.91, 20.68)	(17.86, 23.66)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.97 (2.081)
95% C.I.		(-1.12, 7.05)
p-value		0.155
Corrected Hedge’s g (SE) [3]		0.14 (0.097)
95% C.I.		(-0.05, 0.33)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Mental Health (0-100 score)
Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	207	215
LS Mean (SE)	72.86 (1.505)	74.07 (1.476)
95% C.I.	(69.90, 75.82)	(71.17, 76.98)
LS Mean Change from Baseline (SE)	14.32 (1.505)	15.53 (1.476)
95% C.I.	(11.36, 17.28)	(12.63, 18.43)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		1.21 (2.108)
95% C.I.		(-2.93, 5.36)
p-value		0.565
Corrected Hedge’s g (SE) [3]		0.06 (0.097)
95% C.I.		(-0.13, 0.25)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Mental Health (0-100 score)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	215	209
LS Mean (SE)	74.73 (1.419)	78.99 (1.431)
95% C.I.	(71.95, 77.52)	(76.18, 81.80)
LS Mean Change from Baseline (SE)	16.19 (1.419)	20.45 (1.431)
95% C.I.	(13.40, 18.98)	(17.64, 23.26)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.26 (2.016)
95% C.I.		(0.30, 8.22)
p-value		0.035
Corrected Hedge’s g (SE) [3]		0.20 (0.097)
95% C.I.		(0.01, 0.40)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Physical Component Summary
Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	207	215
LS Mean (SE)	48.77 (0.520)	50.41 (0.510)
95% C.I.	(47.74, 49.79)	(49.41, 51.41)
LS Mean Change from Baseline (SE)	4.77 (0.520)	6.42 (0.510)
95% C.I.	(3.75, 5.80)	(5.41, 7.42)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		1.64 (0.729)
95% C.I.		(0.21, 3.07)
p-value		0.025
Corrected Hedge’s g (SE) [3]		0.22 (0.098)
95% C.I.		(0.03, 0.41)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Physical Component Summary
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	215	209
LS Mean (SE)	51.26 (0.470)	51.12 (0.472)
95% C.I.	(50.33, 52.18)	(50.19, 52.05)
LS Mean Change from Baseline (SE)	7.26 (0.470)	7.13 (0.472)
95% C.I.	(6.34, 8.19)	(6.20, 8.06)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.14 (0.667)
95% C.I.		(-1.45, 1.18)
p-value		0.839
Corrected Hedge’s g (SE) [3]		-0.02 (0.097)
95% C.I.		(-0.21, 0.17)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Mental Component Summary
Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	207	215
LS Mean (SE)	49.75 (0.639)	50.97 (0.627)
95% C.I.	(48.50, 51.01)	(49.74, 52.20)
LS Mean Change from Baseline (SE)	7.15 (0.639)	8.36 (0.627)
95% C.I.	(5.89, 8.40)	(7.13, 9.60)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		1.22 (0.895)
95% C.I.		(-0.54, 2.98)
p-value		0.174
Corrected Hedge’s g (SE) [3]		0.13 (0.097)
95% C.I.		(-0.06, 0.32)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Mental Component Summary
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	215	209
LS Mean (SE)	51.45 (0.613)	53.67 (0.618)
95% C.I.	(50.24, 52.65)	(52.46, 54.89)
LS Mean Change from Baseline (SE)	8.84 (0.613)	11.07 (0.618)
95% C.I.	(7.64, 10.05)	(9.85, 12.28)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.22 (0.871)
95% C.I.		(0.51, 3.93)
p-value		0.011
Corrected Hedge’s g (SE) [3]		0.25 (0.098)
95% C.I.		(0.06, 0.44)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Health Utility Index
Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	264
n [2]	207	212
LS Mean (SE)	0.75 (0.010)	0.79 (0.009)
95% C.I.	(0.73, 0.77)	(0.77, 0.81)
LS Mean Change from Baseline (SE)	0.11 (0.010)	0.15 (0.009)
95% C.I.	(0.09, 0.13)	(0.13, 0.17)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.04 (0.014)
95% C.I.		(0.01, 0.06)
p-value		0.005
Corrected Hedge’s g (SE) [3]		0.28 (0.098)
95% C.I.		(0.08, 0.47)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Health Utility Index
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	264
n [2]	215	209
LS Mean (SE)	0.80 (0.010)	0.83 (0.010)
95% C.I.	(0.78, 0.82)	(0.81, 0.85)
LS Mean Change from Baseline (SE)	0.15 (0.010)	0.19 (0.010)
95% C.I.	(0.13, 0.17)	(0.17, 0.21)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.04 (0.014)
95% C.I.		(0.01, 0.06)
p-value		0.008
Corrected Hedge’s g (SE) [3]		0.26 (0.098)
95% C.I.		(0.07, 0.45)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Role Physical Enhanced (0-100 score)
Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	207	215
LS Mean (SE)	69.89 (1.689)	76.33 (1.657)
95% C.I.	(66.57, 73.21)	(73.07, 79.58)
LS Mean Change from Baseline (SE)	20.99 (1.689)	27.43 (1.657)
95% C.I.	(17.68, 24.31)	(24.18, 30.69)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		6.44 (2.366)
95% C.I.		(1.79, 11.09)
p-value		0.007
Corrected Hedge’s g (SE) [3]		0.26 (0.098)
95% C.I.		(0.07, 0.46)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Role Physical Enhanced (0-100 score)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	215	209
LS Mean (SE)	78.79 (1.501)	82.15 (1.509)
95% C.I.	(75.84, 81.74)	(79.19, 85.11)
LS Mean Change from Baseline (SE)	29.89 (1.501)	33.25 (1.509)
95% C.I.	(26.94, 32.85)	(30.29, 36.22)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.36 (2.129)
95% C.I.		(-0.82, 7.54)
p-value		0.115
Corrected Hedge’s g (SE) [3]		0.15 (0.097)
95% C.I.		(-0.04, 0.34)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Vitality Enhanced (0-100 score)
Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	207	215
LS Mean (SE)	61.98 (1.630)	65.08 (1.599)
95% C.I.	(58.78, 65.19)	(61.94, 68.22)
LS Mean Change from Baseline (SE)	22.44 (1.630)	25.54 (1.599)
95% C.I.	(19.24, 25.65)	(22.40, 28.68)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.10 (2.283)
95% C.I.		(-1.39, 7.58)
p-value		0.176
Corrected Hedge’s g (SE) [3]		0.13 (0.097)
95% C.I.		(-0.06, 0.32)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.8
Analysis of Change from Baseline in SF-12 Hybrid at Day 15 and Day 29

Domain: Vitality Enhanced (0-100 score)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	255	266
n [2]	215	209
LS Mean (SE)	67.29 (1.540)	71.31 (1.544)
95% C.I.	(64.26, 70.32)	(68.27, 74.34)
LS Mean Change from Baseline (SE)	27.75 (1.540)	31.77 (1.544)
95% C.I.	(24.72, 30.78)	(28.74, 34.80)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.02 (2.181)
95% C.I.		(-0.27, 8.31)
p-value		0.066
Corrected Hedge’s g (SE) [3]		0.18 (0.097)
95% C.I.		(-0.01, 0.37)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

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Population: Intent-to-Treat Data as of 27APR2021

Table 24.9
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 15 and Day 29 - GBA Approach

Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	84 (16%)	94 (18%)
Non-responder	123 (23%)	121 (23%)
Missing [1]	322 (61%)	313 (59%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.87
95% C.I.		(0.63, 1.20)
p-value		0.404
Inverse Relative Risk [3]		0.89
95% C.I.		(0.68, 1.17)
p-value		0.404
Risk Difference (%) [4]		-1.92
95% C.I.		(-6.43, 2.59)
p-value		0.413

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

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Table 24.9
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 15 and Day 29 - GBA Approach

Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	92 (17%)	112 (21%)
Non-responder	123 (23%)	97 (18%)
Missing [1]	314 (59%)	319 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.78
95% C.I.		(0.58, 1.06)
p-value		0.117
Inverse Relative Risk [3]		0.82
95% C.I.		(0.64, 1.05)
p-value		0.117
Risk Difference (%) [4]		-3.82
95% C.I.		(-8.57, 0.93)
p-value		0.120

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.10
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 15 and Day 29 - GBA Approach

Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	52 (10%)	95 (18%)
Non-responder	155 (29%)	120 (23%)
Missing [1]	322 (61%)	313 (59%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.50
95% C.I.		(0.35, 0.71)
p-value		<0.001
Inverse Relative Risk [3]		0.55
95% C.I.		(0.40, 0.75)
p-value		<0.001
Risk Difference (%) [4]		-8.16
95% C.I.		(-12.31, -4.02)
p-value		<0.001

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

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Table 24.10
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 15 and Day 29 - GBA Approach

Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	83 (16%)	96 (18%)
Non-responder	132 (25%)	113 (21%)
Missing [1]	314 (59%)	319 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.84
95% C.I.		(0.61, 1.16)
p-value		0.281
Inverse Relative Risk [3]		0.86
95% C.I.		(0.66, 1.13)
p-value		0.281
Risk Difference (%) [4]		-2.49
95% C.I.		(-7.01, 2.03)
p-value		0.288

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

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Population: Intent-to-Treat Data as of 27APR2021

Table 24.11
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 15 and Day 29 - QualityMetric Approach

Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	100 (19%)	110 (21%)
Non-responder	107 (20%)	105 (20%)
Missing [1]	322 (61%)	313 (59%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.89
95% C.I.		(0.65, 1.20)
p-value		0.432
Inverse Relative Risk [3]		0.91
95% C.I.		(0.71, 1.16)
p-value		0.433
Risk Difference (%) [4]		-1.93
95% C.I.		(-6.74, 2.88)
p-value		0.442

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 7 (QualityMetric Approach).

PPD

Table 24.11
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 15 and Day 29 - QualityMetric Approach

Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	113 (21%)	127 (24%)
Non-responder	102 (19%)	82 (16%)
Missing [1]	314 (59%)	319 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.86
95% C.I.		(0.64, 1.14)
p-value		0.297
Inverse Relative Risk [3]		0.89
95% C.I.		(0.71, 1.11)
p-value		0.297
Risk Difference (%) [4]		-2.69
95% C.I.		(-7.74, 2.36)
p-value		0.305

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 7 (QualityMetric Approach).

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.12
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 15 and Day 29 - QualityMetric Approach

Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	81 (15%)	116 (22%)
Non-responder	126 (24%)	99 (19%)
Missing [1]	322 (61%)	313 (59%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.64
95% C.I.		(0.47, 0.88)
p-value		0.006
Inverse Relative Risk [3]		0.70
95% C.I.		(0.54, 0.90)
p-value		0.006
Risk Difference (%) [4]		-6.66
95% C.I.		(-11.34, -1.98)
p-value		0.006

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 6 (QualityMetric Approach).

PPD

Table 24.12
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 15 and Day 29 - QualityMetric Approach

Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	104 (20%)	115 (22%)
Non-responder	111 (21%)	94 (18%)
Missing [1]	314 (59%)	319 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.88
95% C.I.		(0.65, 1.18)
p-value		0.396
Inverse Relative Risk [3]		0.90
95% C.I.		(0.71, 1.14)
p-value		0.396
Risk Difference (%) [4]		-2.12
95% C.I.		(-7.01, 2.76)
p-value		0.405

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 6 (QualityMetric Approach).

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	402	410
		Mean	56.17	57.50
		SD	33.566	33.539
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Week 8	SF-12 Score	n	255	245
		Mean	82.08	82.86
		SD	26.908	26.914
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	221	219
		Mean	27.67	24.32
		SD	35.700	35.105
		Median	25.00	25.00
		Min.	-50.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	269	261
		Mean	82.55	83.43
		SD	26.801	25.959
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	228	230
		Mean	26.89	24.57
		SD	33.935	35.507
		Median	25.00	25.00
		Min.	-75.0	-75.0
		Max.	100.0	100.0
Week 16	SF-12 Score	n	72	67
		Mean	83.97	87.26
		SD	30.029	23.958
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	60	56
		Mean	28.90	23.59
		SD	33.024	42.527
		Median	25.00	0.00
		Min.	-25.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	167	165
		Mean	84.28	82.35
		SD	26.955	28.147
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	144	143
		Mean	28.19	21.41
		SD	34.420	39.762
		Median	25.00	0.00
		Min.	-75.0	-100.0
		Max.	100.0	100.0
Week 24	SF-12 Score	n	191	182
		Mean	82.90	83.33
		SD	29.245	25.407
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	164	159
		Mean	28.00	23.37
		SD	34.234	36.786
		Median	25.00	25.00
		Min.	-50.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	402	410
		Mean	43.26	43.68
		SD	10.567	10.558
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Week 8	SF-12 Score	n	255	245
		Mean	51.42	51.66
		SD	8.471	8.473
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	221	219
		Mean	8.71	7.65
		SD	11.238	11.051
		Median	7.87	7.87
		Min.	-15.7	-31.5
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	269	261
		Mean	51.57	51.84
		SD	8.437	8.172
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	228	230
		Mean	8.47	7.73
		SD	10.683	11.178
		Median	7.87	7.87
		Min.	-23.6	-23.6
		Max.	31.5	31.5
Week 16	SF-12 Score	n	72	67
		Mean	52.02	53.05
		SD	9.453	7.542
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	60	56
		Mean	9.10	7.43
		SD	10.396	13.387
		Median	7.87	0.00
		Min.	-7.9	-31.5
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.

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Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	167	165
		Mean	52.11	51.50
		SD	8.486	8.861
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	144	143
		Mean	8.87	6.74
		SD	10.836	12.517
		Median	7.87	0.00
		Min.	-23.6	-31.5
		Max.	31.5	31.5
Week 24	SF-12 Score	n	191	182
		Mean	51.68	51.81
		SD	9.207	7.998
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	164	159
		Mean	8.81	7.36
		SD	10.777	11.580
		Median	7.87	7.87
		Min.	-15.7	-15.7
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	50.09	52.01
		SD	27.550	28.575
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Week 8	SF-12 Score	n	255	245
		Mean	79.95	83.57
		SD	24.263	23.934
		Median	87.50	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	221	219
		Mean	30.94	29.10
		SD	30.375	31.270
		Median	25.00	36.32
		Min.	-62.5	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	269	261
		Mean	80.02	82.66
		SD	25.629	23.968
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	228	230
		Mean	30.92	28.86
		SD	28.461	33.155
		Median	25.00	25.00
		Min.	-25.0	-62.5
		Max.	100.0	100.0
Week 16	SF-12 Score	n	72	67
		Mean	84.90	89.74
		SD	27.025	20.404
		Median	100.00	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	60	56
		Mean	32.92	31.03
		SD	34.672	33.370
		Median	25.00	37.50
		Min.	-25.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	167	164
		Mean	86.01	84.25
		SD	22.263	24.849
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	144	142
		Mean	35.34	28.69
		SD	34.088	33.740
		Median	25.00	25.00
		Min.	-50.0	-62.5
		Max.	100.0	100.0
Week 24	SF-12 Score	n	190	182
		Mean	85.17	86.28
		SD	22.556	22.802
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	163	159
		Mean	34.55	30.68
		SD	31.215	33.115
		Median	37.50	25.00
		Min.	-37.5	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	40.57	41.22
		SD	9.326	9.674
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Week 8	SF-12 Score	n	255	245
		Mean	50.67	51.90
		SD	8.213	8.101
		Median	53.23	57.46
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	221	219
		Mean	10.47	9.85
		SD	10.282	10.585
		Median	8.47	12.29
		Min.	-21.2	-16.9
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	269	261
		Mean	50.70	51.59
		SD	8.675	8.113
		Median	57.46	57.46
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	228	230
		Mean	10.47	9.77
		SD	9.634	11.223
		Median	8.47	8.47
		Min.	-8.5	-21.2
		Max.	33.9	33.9
Week 16	SF-12 Score	n	72	67
		Mean	52.35	53.99
		SD	9.148	6.906
		Median	57.46	57.46
		Min.	23.6	32.1
		Max.	57.5	57.5
	Change from Baseline	n	60	56
		Mean	11.14	10.50
		SD	11.737	11.296
		Median	8.46	12.69
		Min.	-8.5	-16.9
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	167	164
		Mean	52.73	52.13
		SD	7.535	8.411
		Median	57.46	57.46
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	144	142
		Mean	11.96	9.71
		SD	11.539	11.422
		Median	8.47	8.46
		Min.	-16.9	-21.2
		Max.	33.9	33.9
Week 24	SF-12 Score	n	190	182
		Mean	52.44	52.82
		SD	7.635	7.718
		Median	57.46	57.46
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	163	159
		Mean	11.70	10.39
		SD	10.567	11.210
		Median	12.69	8.46
		Min.	-12.7	-25.4
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	400	409
		Mean	62.31	60.70
		SD	29.298	30.371
		Median	75.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Week 8	SF-12 Score	n	255	245
		Mean	84.02	87.14
		SD	24.941	23.369
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	221	218
		Mean	22.17	25.69
		SD	34.958	33.765
		Median	25.00	25.00
		Min.	-100.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	268	259
		Mean	86.75	87.84
		SD	23.542	22.593
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	228	227
		Mean	23.36	26.32
		SD	34.248	34.778
		Median	25.00	25.00
		Min.	-100.0	-75.0
		Max.	100.0	100.0
Week 16	SF-12 Score	n	72	67
		Mean	84.38	92.91
		SD	26.014	17.302
		Median	100.00	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	60	56
		Mean	23.33	28.57
		SD	35.014	37.667
		Median	25.00	25.00
		Min.	-75.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	165	164
		Mean	87.88	87.50
		SD	21.844	22.752
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	142	141
		Mean	23.77	23.76
		SD	33.066	35.773
		Median	25.00	25.00
		Min.	-100.0	-100.0
		Max.	100.0	100.0
Week 24	SF-12 Score	n	189	180
		Mean	87.57	86.39
		SD	22.718	22.628
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	162	156
		Mean	23.92	24.04
		SD	33.593	34.883
		Median	25.00	25.00
		Min.	-100.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	400	409
		Mean	44.13	43.55
		SD	10.570	10.956
		Median	48.71	39.69
		Min.	21.7	21.7
		Max.	57.7	57.7
Week 8	SF-12 Score	n	255	245
		Mean	51.96	53.09
		SD	8.998	8.431
		Median	57.73	57.73
		Min.	21.7	21.7
		Max.	57.7	57.7
	Change from Baseline	n	221	218
		Mean	8.00	9.27
		SD	12.612	12.181
		Median	9.02	9.02
		Min.	-36.1	-36.1
		Max.	36.1	36.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	268	259
		Mean	52.95	53.34
		SD	8.493	8.151
		Median	57.73	57.73
		Min.	21.7	21.7
		Max.	57.7	57.7
	Change from Baseline	n	228	227
		Mean	8.43	9.50
		SD	12.356	12.547
		Median	9.02	9.02
		Min.	-36.1	-27.1
		Max.	36.1	36.1
Week 16	SF-12 Score	n	72	67
		Mean	52.09	55.17
		SD	9.385	6.243
		Median	57.73	57.73
		Min.	21.7	30.7
		Max.	57.7	57.7
	Change from Baseline	n	60	56
		Mean	8.42	10.31
		SD	12.632	13.589
		Median	9.02	9.02
		Min.	-27.1	-27.1
		Max.	36.1	36.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	165	164
		Mean	53.36	53.22
		SD	7.881	8.208
		Median	57.73	57.73
		Min.	21.7	21.7
		Max.	57.7	57.7
	Change from Baseline	n	142	141
		Mean	8.57	8.57
		SD	11.929	12.905
		Median	9.02	9.02
		Min.	-36.1	-36.1
		Max.	36.1	36.1
Week 24	SF-12 Score	n	189	180
		Mean	53.24	52.82
		SD	8.196	8.164
		Median	57.73	57.73
		Min.	21.7	21.7
		Max.	57.7	57.7
	Change from Baseline	n	162	156
		Mean	8.63	8.67
		SD	12.119	12.584
		Median	9.02	9.02
		Min.	-36.1	-36.1
		Max.	36.1	36.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: General Health (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	55.61	53.91
		SD	28.257	29.674
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Week 8	SF-12 Score	n	255	244
		Mean	72.39	71.27
		SD	22.161	21.826
		Median	85.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	221	218
		Mean	18.12	15.67
		SD	30.041	33.046
		Median	0.00	0.00
		Min.	-60.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: General Health (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	267	261
		Mean	71.52	72.15
		SD	23.465	21.398
		Median	85.00	85.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	226	230
		Mean	16.02	16.80
		SD	29.901	34.272
		Median	0.00	0.00
		Min.	-75.0	-75.0
		Max.	100.0	100.0
Week 16	SF-12 Score	n	72	67
		Mean	71.04	76.87
		SD	26.642	21.282
		Median	85.00	85.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	60	56
		Mean	15.58	18.21
		SD	31.097	33.035
		Median	15.00	15.00
		Min.	-40.0	-40.0
		Max.	85.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: General Health (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	166	164
		Mean	74.43	72.90
		SD	20.018	22.182
		Median	85.00	85.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	143	142
		Mean	15.94	17.57
		SD	30.679	35.459
		Median	15.00	0.00
		Min.	-75.0	-75.0
		Max.	85.0	100.0
Week 24	SF-12 Score	n	189	182
		Mean	72.86	73.76
		SD	21.783	20.871
		Median	85.00	85.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	161	159
		Mean	17.98	17.80
		SD	29.280	36.058
		Median	15.00	0.00
		Min.	-75.0	-60.0
		Max.	85.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: General Health (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	46.01	45.33
		SD	11.233	11.797
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Week 8	SF-12 Score	n	255	244
		Mean	52.68	52.23
		SD	8.811	8.678
		Median	57.69	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
	Change from Baseline	n	221	218
		Mean	7.20	6.23
		SD	11.943	13.138
		Median	0.00	0.00
		Min.	-23.8	-39.8
		Max.	39.8	39.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: General Health (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	267	261
		Mean	52.33	52.58
		SD	9.330	8.508
		Median	57.69	57.69
		Min.	23.9	23.9
		Max.	63.7	63.7
	Change from Baseline	n	226	230
		Mean	6.37	6.68
		SD	11.888	13.625
		Median	0.00	0.00
		Min.	-29.8	-29.8
		Max.	39.8	39.8
Week 16	SF-12 Score	n	72	67
		Mean	52.14	54.46
		SD	10.592	8.462
		Median	57.69	57.69
		Min.	23.9	33.8
		Max.	63.7	63.7
	Change from Baseline	n	60	56
		Mean	6.20	7.24
		SD	12.363	13.134
		Median	5.97	5.97
		Min.	-15.9	-15.9
		Max.	33.8	39.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: General Health (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	166	164
		Mean	53.49	52.88
		SD	7.960	8.820
		Median	57.69	57.69
		Min.	23.9	33.8
		Max.	63.7	63.7
	Change from Baseline	n	143	142
		Mean	6.34	6.99
		SD	12.197	14.097
		Median	5.97	0.00
		Min.	-29.8	-29.8
		Max.	33.8	39.8
Week 24	SF-12 Score	n	189	182
		Mean	52.86	53.22
		SD	8.661	8.299
		Median	57.69	57.69
		Min.	23.9	33.8
		Max.	63.7	63.7
	Change from Baseline	n	161	159
		Mean	7.15	7.08
		SD	11.640	14.335
		Median	5.97	0.00
		Min.	-29.8	-23.8
		Max.	33.8	39.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	36.35	36.04
		SD	27.990	28.164
		Median	25.00	25.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Week 8	SF-12 Score	n	255	244
		Mean	65.39	63.63
		SD	29.859	32.335
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	221	219
		Mean	30.43	29.79
		SD	31.242	36.549
		Median	25.00	25.00
		Min.	-50.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	269	260
		Mean	59.39	61.92
		SD	31.707	31.564
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	228	229
		Mean	25.88	27.84
		SD	36.494	37.208
		Median	25.00	25.00
		Min.	-100.0	-100.0
		Max.	100.0	100.0
Week 16	SF-12 Score	n	72	66
		Mean	60.07	67.80
		SD	32.136	31.245
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	60	55
		Mean	30.00	35.45
		SD	35.295	41.581
		Median	25.00	50.00
		Min.	-75.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	165	164
		Mean	58.79	55.64
		SD	28.665	31.735
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	142	142
		Mean	32.39	27.11
		SD	41.234	39.443
		Median	37.50	25.00
		Min.	-100.0	-100.0
		Max.	100.0	100.0
Week 24	SF-12 Score	n	191	178
		Mean	56.28	57.16
		SD	28.902	29.853
		Median	50.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	164	155
		Mean	26.37	27.10
		SD	38.497	39.678
		Median	25.00	25.00
		Min.	-100.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	43.69	43.57
		SD	11.014	11.083
		Median	39.23	39.23
		Min.	29.4	29.4
		Max.	68.7	68.7
Week 8	SF-12 Score	n	255	244
		Mean	55.12	54.43
		SD	11.748	12.723
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	221	219
		Mean	11.97	11.72
		SD	12.293	14.382
		Median	9.84	9.84
		Min.	-19.7	-39.3
		Max.	39.3	39.3

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	269	260
		Mean	52.76	53.76
		SD	12.475	12.419
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	228	229
		Mean	10.18	10.95
		SD	14.360	14.641
		Median	9.84	9.84
		Min.	-39.3	-39.3
		Max.	39.3	39.3
Week 16	SF-12 Score	n	72	66
		Mean	53.03	56.07
		SD	12.645	12.294
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	60	55
		Mean	11.80	13.95
		SD	13.888	16.361
		Median	9.84	19.67
		Min.	-29.5	-29.5
		Max.	39.3	39.3

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	165	164
		Mean	52.52	51.28
		SD	11.278	12.487
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	142	142
		Mean	12.75	10.67
		SD	16.225	15.520
		Median	14.76	9.84
		Min.	-39.3	-39.3
		Max.	39.3	39.3
Week 24	SF-12 Score	n	191	178
		Mean	51.54	51.88
		SD	11.372	11.746
		Median	49.07	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	164	155
		Mean	10.38	10.66
		SD	15.148	15.613
		Median	9.84	9.84
		Min.	-39.3	-39.3
		Max.	39.3	39.3

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	46.82	46.71
		SD	36.067	35.932
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Week 8	SF-12 Score	n	255	245
		Mean	83.24	86.43
		SD	22.965	23.889
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	221	219
		Mean	37.33	38.93
		SD	38.259	37.175
		Median	50.00	50.00
		Min.	-75.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	267	261
		Mean	83.80	87.16
		SD	25.599	22.850
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	226	230
		Mean	37.94	39.57
		SD	41.246	39.232
		Median	50.00	50.00
		Min.	-100.0	-75.0
		Max.	100.0	100.0
Week 16	SF-12 Score	n	69	67
		Mean	91.67	90.30
		SD	18.021	20.392
		Median	100.00	100.00
		Min.	25.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	59	56
		Mean	45.34	40.63
		SD	42.415	39.761
		Median	50.00	25.00
		Min.	-25.0	-25.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	166	164
		Mean	93.07	89.02
		SD	16.429	21.663
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	143	142
		Mean	46.50	37.50
		SD	40.202	40.906
		Median	50.00	25.00
		Min.	-50.0	-75.0
		Max.	100.0	100.0
Week 24	SF-12 Score	n	189	180
		Mean	91.01	90.56
		SD	18.731	19.447
		Median	100.00	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	162	157
		Mean	41.20	39.01
		SD	40.711	41.151
		Median	50.00	25.00
		Min.	-50.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	37.98	37.94
		SD	12.832	12.785
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Week 8	SF-12 Score	n	255	245
		Mean	50.94	52.07
		SD	8.170	8.499
		Median	56.90	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	221	219
		Mean	13.28	13.85
		SD	13.612	13.227
		Median	17.79	17.79
		Min.	-26.7	-26.7
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	267	261
		Mean	51.14	52.33
		SD	9.107	8.129
		Median	56.90	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	226	230
		Mean	13.50	14.08
		SD	14.675	13.958
		Median	17.79	17.79
		Min.	-35.6	-26.7
		Max.	35.6	35.6
Week 16	SF-12 Score	n	69	67
		Mean	53.94	53.45
		SD	6.411	7.254
		Median	56.90	56.90
		Min.	30.2	30.2
		Max.	56.9	56.9
	Change from Baseline	n	59	56
		Mean	16.13	14.45
		SD	15.091	14.147
		Median	17.79	8.90
		Min.	-8.9	-8.9
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	166	164
		Mean	54.44	53.00
		SD	5.845	7.707
		Median	56.90	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	143	142
		Mean	16.55	13.34
		SD	14.304	14.554
		Median	17.79	8.90
		Min.	-17.8	-26.7
		Max.	35.6	35.6
Week 24	SF-12 Score	n	189	180
		Mean	53.70	53.54
		SD	6.664	6.918
		Median	56.90	56.90
		Min.	21.3	30.2
		Max.	56.9	56.9
	Change from Baseline	n	162	157
		Mean	14.66	13.88
		SD	14.485	14.641
		Median	17.79	8.90
		Min.	-17.8	-17.8
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	64.52	66.59
		SD	28.226	29.527
		Median	62.50	68.75
		Min.	0.0	0.0
		Max.	100.0	100.0
Week 8	SF-12 Score	n	255	245
		Mean	84.22	88.61
		SD	22.203	20.367
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	221	219
		Mean	21.95	20.02
		SD	27.699	28.493
		Median	12.50	12.50
		Min.	-50.0	-62.5
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	269	261
		Mean	83.27	88.31
		SD	24.792	19.854
		Median	100.00	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	228	230
		Mean	18.32	18.64
		SD	29.100	28.964
		Median	12.50	12.50
		Min.	-87.5	-50.0
		Max.	100.0	100.0
Week 16	SF-12 Score	n	72	67
		Mean	88.19	91.87
		SD	20.863	16.784
		Median	100.00	100.00
		Min.	25.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	60	56
		Mean	24.62	23.98
		SD	32.110	29.385
		Median	18.75	21.55
		Min.	-50.0	-25.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	167	165
		Mean	90.22	89.78
		SD	16.677	18.676
		Median	100.00	100.00
		Min.	25.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	144	143
		Mean	22.27	18.19
		SD	29.585	31.442
		Median	12.50	12.50
		Min.	-37.5	-62.5
		Max.	100.0	100.0
Week 24	SF-12 Score	n	191	182
		Mean	90.35	90.18
		SD	17.726	16.924
		Median	100.00	100.00
		Min.	25.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	164	159
		Mean	22.76	17.22
		SD	28.522	27.981
		Median	12.50	12.50
		Min.	-50.0	-62.5
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	41.53	42.39
		SD	11.738	12.278
		Median	40.69	43.29
		Min.	14.7	14.7
		Max.	56.3	56.3
Week 8	SF-12 Score	n	255	245
		Mean	49.72	51.55
		SD	9.232	8.468
		Median	56.28	56.28
		Min.	14.7	14.7
		Max.	56.3	56.3
	Change from Baseline	n	221	219
		Mean	9.13	8.33
		SD	11.518	11.848
		Median	5.20	5.20
		Min.	-20.8	-26.0
		Max.	41.6	41.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	269	261
		Mean	49.32	51.42
		SD	10.309	8.255
		Median	56.28	56.28
		Min.	14.7	25.1
		Max.	56.3	56.3
	Change from Baseline	n	228	230
		Mean	7.62	7.75
		SD	12.101	12.044
		Median	5.20	5.20
		Min.	-36.4	-20.8
		Max.	41.6	41.6
Week 16	SF-12 Score	n	72	67
		Mean	51.37	52.90
		SD	8.675	6.979
		Median	56.28	56.28
		Min.	25.1	25.1
		Max.	56.3	56.3
	Change from Baseline	n	60	56
		Mean	10.24	9.97
		SD	13.352	12.218
		Median	7.80	8.96
		Min.	-20.8	-10.4
		Max.	41.6	41.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	167	165
		Mean	52.21	52.03
		SD	6.934	7.766
		Median	56.28	56.28
		Min.	25.1	25.1
		Max.	56.3	56.3
	Change from Baseline	n	144	143
		Mean	9.26	7.56
		SD	12.302	13.075
		Median	5.20	5.20
		Min.	-15.6	-26.0
		Max.	41.6	41.6
Week 24	SF-12 Score	n	191	182
		Mean	52.27	52.20
		SD	7.371	7.037
		Median	56.28	56.28
		Min.	25.1	25.1
		Max.	56.3	56.3
	Change from Baseline	n	164	159
		Mean	9.47	7.16
		SD	11.860	11.635
		Median	5.20	5.20
		Min.	-20.8	-26.0
		Max.	41.6	41.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	58.39	59.12
		SD	22.660	23.850
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Week 8	SF-12 Score	n	255	245
		Mean	75.69	76.48
		SD	21.668	23.625
		Median	87.50	87.50
		Min.	12.5	0.0
		Max.	100.0	100.0
	Change from Baseline	n	221	219
		Mean	18.83	18.09
		SD	25.883	29.524
		Median	12.50	12.50
		Min.	-50.0	-50.0
		Max.	87.5	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	269	261
		Mean	74.74	77.49
		SD	22.884	21.592
		Median	87.50	87.50
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	228	230
		Mean	16.47	16.64
		SD	27.194	28.214
		Median	12.50	12.50
		Min.	-62.5	-50.0
		Max.	100.0	87.5
Week 16	SF-12 Score	n	72	67
		Mean	76.30	80.97
		SD	20.798	19.747
		Median	87.50	87.50
		Min.	25.0	37.5
		Max.	100.0	100.0
	Change from Baseline	n	60	56
		Mean	20.00	23.21
		SD	26.160	27.223
		Median	12.50	25.00
		Min.	-25.0	-37.5
		Max.	75.0	87.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	166	164
		Mean	83.13	78.81
		SD	18.758	21.008
		Median	87.50	87.50
		Min.	12.5	0.0
		Max.	100.0	100.0
	Change from Baseline	n	143	142
		Mean	23.34	18.39
		SD	26.918	26.381
		Median	25.00	12.50
		Min.	-50.0	-50.0
		Max.	87.5	87.5
Week 24	SF-12 Score	n	192	182
		Mean	79.55	80.01
		SD	18.847	20.117
		Median	87.50	87.50
		Min.	25.0	12.5
		Max.	100.0	100.0
	Change from Baseline	n	165	159
		Mean	19.31	17.44
		SD	25.761	28.092
		Median	12.50	12.50
		Min.	-50.0	-62.5
		Max.	87.5	87.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	45.11	45.45
		SD	10.399	10.945
		Median	41.26	41.26
		Min.	18.3	18.3
		Max.	64.2	64.2
Week 8	SF-12 Score	n	255	245
		Mean	53.05	53.41
		SD	9.944	10.842
		Median	58.47	58.47
		Min.	24.1	18.3
		Max.	64.2	64.2
	Change from Baseline	n	221	219
		Mean	8.64	8.30
		SD	11.878	13.550
		Median	5.74	5.74
		Min.	-23.0	-23.0
		Max.	40.2	45.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	269	261
		Mean	52.62	53.88
		SD	10.502	9.909
		Median	58.47	58.47
		Min.	18.3	18.3
		Max.	64.2	64.2
	Change from Baseline	n	228	230
		Mean	7.56	7.63
		SD	12.480	12.948
		Median	5.74	5.74
		Min.	-28.7	-23.0
		Max.	45.9	40.1
Week 16	SF-12 Score	n	72	67
		Mean	53.33	55.48
		SD	9.545	9.062
		Median	58.47	58.47
		Min.	29.8	35.5
		Max.	64.2	64.2
	Change from Baseline	n	60	56
		Mean	9.18	10.65
		SD	12.005	12.492
		Median	5.74	11.47
		Min.	-11.5	-17.2
		Max.	34.4	40.1

Note: SF-12 was scheduled for the Expansion phase only.

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	166	164
		Mean	56.47	54.48
		SD	8.608	9.641
		Median	58.47	58.47
		Min.	24.1	18.3
		Max.	64.2	64.2
	Change from Baseline	n	143	142
		Mean	10.71	8.44
		SD	12.352	12.107
		Median	11.47	5.74
		Min.	-23.0	-23.0
		Max.	40.1	40.1
Week 24	SF-12 Score	n	192	182
		Mean	54.83	55.03
		SD	8.649	9.232
		Median	58.47	58.47
		Min.	29.8	24.1
		Max.	64.2	64.2
	Change from Baseline	n	165	159
		Mean	8.86	8.01
		SD	11.822	12.892
		Median	5.74	5.74
		Min.	-23.0	-28.7
		Max.	40.1	40.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Physical Component Summary

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	43.58	43.39
		SD	9.068	8.887
		Median	43.90	43.93
		Min.	17.4	20.2
		Max.	62.6	64.6
Week 8	SF-12 Score	n	255	245
		Mean	51.65	51.98
		SD	7.972	8.267
		Median	54.10	53.80
		Min.	27.9	16.6
		Max.	63.8	69.1
	Change from Baseline	n	221	219
		Mean	8.29	7.98
		SD	10.013	9.932
		Median	6.93	8.41
		Min.	-18.7	-26.6
		Max.	37.1	34.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Physical Component Summary

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	269	260
		Mean	52.05	52.05
		SD	7.931	7.556
		Median	54.64	54.63
		Min.	24.7	22.5
		Max.	63.8	66.9
	Change from Baseline	n	228	229
		Mean	8.57	8.47
		SD	9.605	10.125
		Median	8.40	8.69
		Min.	-12.8	-20.4
		Max.	42.1	33.6
Week 16	SF-12 Score	n	72	67
		Mean	51.94	53.85
		SD	9.200	6.277
		Median	55.99	56.68
		Min.	25.7	30.7
		Max.	62.6	62.7
	Change from Baseline	n	60	56
		Mean	8.22	8.01
		SD	10.431	11.248
		Median	5.23	5.76
		Min.	-7.0	-12.7
		Max.	38.8	32.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Physical Component Summary

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	165	164
		Mean	52.13	51.76
		SD	7.498	7.707
		Median	54.49	54.46
		Min.	24.8	20.2
		Max.	62.6	62.3
	Change from Baseline	n	142	142
		Mean	8.49	7.64
		SD	10.220	10.589
		Median	7.23	6.36
		Min.	-26.8	-20.6
		Max.	36.6	33.6
Week 24	SF-12 Score	n	190	180
		Mean	51.92	51.98
		SD	8.061	6.982
		Median	54.64	54.35
		Min.	22.6	26.2
		Max.	64.1	62.5
	Change from Baseline	n	163	157
		Mean	8.80	8.37
		SD	9.961	9.856
		Median	8.28	7.67
		Min.	-20.0	-17.7
		Max.	38.5	31.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Mental Component Summary

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	42.58	42.97
		SD	10.183	10.418
		Median	41.81	41.91
		Min.	13.8	11.0
		Max.	73.0	69.3
Week 8	SF-12 Score	n	255	245
		Mean	52.17	52.97
		SD	9.104	9.697
		Median	54.12	55.77
		Min.	24.3	15.3
		Max.	66.0	67.3
	Change from Baseline	n	221	219
		Mean	10.36	10.16
		SD	10.943	11.559
		Median	10.28	10.39
		Min.	-26.7	-22.5
		Max.	42.0	41.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Mental Component Summary

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	269	260
		Mean	51.18	53.01
		SD	10.174	9.068
		Median	54.59	54.89
		Min.	15.0	24.0
		Max.	69.3	67.8
	Change from Baseline	n	228	229
		Mean	8.88	9.47
		SD	12.037	11.441
		Median	8.17	8.86
		Min.	-36.3	-28.8
		Max.	46.8	41.4
Week 16	SF-12 Score	n	72	67
		Mean	52.94	54.45
		SD	8.594	8.651
		Median	57.28	57.38
		Min.	29.7	31.1
		Max.	64.1	67.1
	Change from Baseline	n	60	56
		Mean	11.66	12.50
		SD	11.476	11.544
		Median	10.00	11.90
		Min.	-9.4	-14.1
		Max.	39.7	34.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Mental Component Summary

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	165	164
		Mean	54.64	53.20
		SD	7.560	8.799
		Median	57.28	56.65
		Min.	25.4	22.1
		Max.	66.6	73.0
	Change from Baseline	n	142	142
		Mean	12.17	9.82
		SD	11.485	11.356
		Median	11.01	8.75
		Min.	-15.1	-17.7
		Max.	46.6	41.4
Week 24	SF-12 Score	n	190	180
		Mean	53.75	53.72
		SD	7.760	8.487
		Median	55.51	55.98
		Min.	21.7	20.1
		Max.	69.8	67.9
	Change from Baseline	n	163	157
		Mean	10.56	9.45
		SD	11.235	11.254
		Median	9.78	8.81
		Min.	-16.6	-22.9
		Max.	44.8	36.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Health Utility Index

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	400	409
		Mean	0.642	0.641
		SD	0.1231	0.1305
		Median	0.619	0.618
		Min.	0.35	0.35
		Max.	1.00	1.00
Week 8	SF-12 Score	n	255	243
		Mean	0.802	0.828
		SD	0.1498	0.1537
		Median	0.800	0.863
		Min.	0.42	0.47
		Max.	1.00	1.00
	Change from Baseline	n	221	217
		Mean	0.167	0.184
		SD	0.1681	0.1714
		Median	0.168	0.198
		Min.	-0.36	-0.20
		Max.	0.52	0.63

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Health Utility Index

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	264	259
		Mean	0.803	0.827
		SD	0.1478	0.1402
		Median	0.817	0.859
		Min.	0.38	0.45
		Max.	1.00	1.00
	Change from Baseline	n	224	227
		Mean	0.164	0.183
		SD	0.1644	0.1716
		Median	0.168	0.196
		Min.	-0.32	-0.22
		Max.	0.49	0.63
Week 16	SF-12 Score	n	68	64
		Mean	0.833	0.868
		SD	0.1527	0.1296
		Median	0.922	0.922
		Min.	0.44	0.49
		Max.	1.00	1.00
	Change from Baseline	n	59	53
		Mean	0.196	0.213
		SD	0.1630	0.1704
		Median	0.200	0.218
		Min.	-0.34	-0.26
		Max.	0.52	0.57

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Health Utility Index

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	163	159
		Mean	0.839	0.826
		SD	0.1240	0.1372
		Median	0.863	0.859
		Min.	0.37	0.35
		Max.	1.00	1.00
	Change from Baseline	n	140	136
		Mean	0.199	0.179
		SD	0.1435	0.1597
		Median	0.190	0.183
		Min.	-0.13	-0.26
		Max.	0.55	0.54
Week 24	SF-12 Score	n	181	173
		Mean	0.822	0.829
		SD	0.1299	0.1336
		Median	0.859	0.863
		Min.	0.45	0.46
		Max.	1.00	1.00
	Change from Baseline	n	154	149
		Mean	0.177	0.178
		SD	0.1400	0.1626
		Median	0.185	0.185
		Min.	-0.14	-0.28
		Max.	0.45	0.54

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	48.47	49.15
		SD	26.487	27.728
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Week 8	SF-12 Score	n	255	245
		Mean	81.05	84.46
		SD	22.356	22.702
		Median	87.50	100.00
		Min.	6.3	6.3
		Max.	100.0	100.0
	Change from Baseline	n	221	219
		Mean	33.88	33.53
		SD	28.216	29.850
		Median	37.50	37.50
		Min.	-37.5	-56.3
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	269	261
		Mean	81.30	84.09
		SD	23.342	21.887
		Median	93.75	100.00
		Min.	12.5	6.3
		Max.	100.0	100.0
	Change from Baseline	n	228	230
		Mean	33.61	33.83
		SD	27.683	30.231
		Median	37.50	37.50
		Min.	-25.0	-50.0
		Max.	100.0	100.0
Week 16	SF-12 Score	n	72	67
		Mean	85.68	89.83
		SD	24.566	19.151
		Median	100.00	100.00
		Min.	6.3	25.0
		Max.	100.0	100.0
	Change from Baseline	n	60	56
		Mean	35.83	33.93
		SD	31.949	32.897
		Median	34.38	34.38
		Min.	-18.8	-31.3
		Max.	100.0	93.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	167	165
		Mean	86.99	84.72
		SD	19.329	22.534
		Median	100.00	100.00
		Min.	6.3	12.5
		Max.	100.0	100.0
	Change from Baseline	n	144	143
		Mean	38.25	32.34
		SD	29.577	31.481
		Median	37.50	31.25
		Min.	-25.0	-50.0
		Max.	100.0	100.0
Week 24	SF-12 Score	n	191	183
		Mean	86.34	86.82
		SD	20.702	20.821
		Median	100.00	100.00
		Min.	18.8	6.3
		Max.	100.0	100.0
	Change from Baseline	n	164	160
		Mean	36.95	34.49
		SD	29.684	31.838
		Median	37.50	31.25
		Min.	-31.3	-56.3
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	38.64	38.89
		SD	9.516	9.962
		Median	39.19	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Week 8	SF-12 Score	n	255	245
		Mean	50.35	51.58
		SD	8.033	8.158
		Median	52.66	57.16
		Min.	23.5	23.5
		Max.	57.2	57.2
	Change from Baseline	n	221	219
		Mean	12.17	12.05
		SD	10.138	10.725
		Median	13.47	13.47
		Min.	-13.5	-20.2
		Max.	35.9	35.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	269	261
		Mean	50.44	51.44
		SD	8.388	7.865
		Median	54.91	57.16
		Min.	25.7	23.5
		Max.	57.2	57.2
	Change from Baseline	n	228	230
		Mean	12.08	12.16
		SD	9.947	10.862
		Median	13.47	13.47
		Min.	-9.0	-18.0
		Max.	35.9	35.9
Week 16	SF-12 Score	n	72	67
		Mean	52.01	53.51
		SD	8.828	6.882
		Median	57.16	57.16
		Min.	23.5	30.2
		Max.	57.2	57.2
	Change from Baseline	n	60	56
		Mean	12.88	12.19
		SD	11.479	11.820
		Median	12.35	12.35
		Min.	-6.7	-11.2
		Max.	35.9	33.7

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	167	165
		Mean	52.48	51.67
		SD	6.946	8.097
		Median	57.16	57.16
		Min.	23.5	25.7
		Max.	57.2	57.2
	Change from Baseline	n	144	143
		Mean	13.75	11.62
		SD	10.627	11.311
		Median	13.48	11.23
		Min.	-9.0	-18.0
		Max.	35.9	35.9
Week 24	SF-12 Score	n	191	183
		Mean	52.25	52.42
		SD	7.439	7.482
		Median	57.16	57.16
		Min.	28.0	23.5
		Max.	57.2	57.2
	Change from Baseline	n	164	160
		Mean	13.28	12.39
		SD	10.665	11.439
		Median	13.48	11.23
		Min.	-11.2	-20.2
		Max.	35.9	35.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	40.70	40.29
		SD	24.243	24.765
		Median	43.75	43.75
		Min.	0.0	0.0
		Max.	100.0	100.0
Week 8	SF-12 Score	n	255	245
		Mean	71.03	69.61
		SD	23.481	26.446
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	221	219
		Mean	31.93	30.49
		SD	26.103	27.203
		Median	31.25	31.25
		Min.	-43.8	-56.3
		Max.	93.8	93.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	269	261
		Mean	66.64	69.68
		SD	24.901	23.911
		Median	68.75	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	228	230
		Mean	28.23	30.48
		SD	26.623	26.927
		Median	25.00	31.25
		Min.	-50.0	-50.0
		Max.	93.8	100.0
Week 16	SF-12 Score	n	72	67
		Mean	67.88	73.69
		SD	25.051	25.851
		Median	75.00	81.25
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	60	56
		Mean	31.35	34.93
		SD	24.640	31.752
		Median	31.25	37.50
		Min.	-31.3	-43.8
		Max.	93.8	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	166	165
		Mean	69.35	64.24
		SD	21.361	26.169
		Median	75.00	68.75
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	143	143
		Mean	35.31	28.28
		SD	26.256	29.779
		Median	37.50	25.00
		Min.	-25.0	-50.0
		Max.	93.8	93.8
Week 24	SF-12 Score	n	192	183
		Mean	65.53	65.77
		SD	22.684	24.511
		Median	68.75	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	165	160
		Mean	29.58	29.44
		SD	28.592	28.773
		Median	25.00	31.25
		Min.	-56.3	-50.0
		Max.	93.8	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	401	410
		Mean	42.23	42.04
		SD	11.524	11.772
		Median	43.69	43.69
		Min.	22.9	22.9
		Max.	70.4	70.4
Week 8	SF-12 Score	n	255	245
		Mean	56.65	55.98
		SD	11.160	12.569
		Median	58.54	58.54
		Min.	22.9	22.9
		Max.	70.4	70.4
	Change from Baseline	n	221	219
		Mean	15.18	14.49
		SD	12.407	12.930
		Median	14.86	14.85
		Min.	-20.8	-26.7
		Max.	44.6	44.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	SF-12 Score	n	269	261
		Mean	54.56	56.01
		SD	11.835	11.364
		Median	55.57	58.54
		Min.	22.9	22.9
		Max.	70.4	70.4
	Change from Baseline	n	228	230
		Mean	13.42	14.49
		SD	12.654	12.799
		Median	11.89	14.85
		Min.	-23.8	-23.8
		Max.	44.6	47.5
Week 16	SF-12 Score	n	72	67
		Mean	55.16	57.92
		SD	11.906	12.287
		Median	58.54	61.51
		Min.	22.9	22.9
		Max.	70.4	70.4
	Change from Baseline	n	60	56
		Mean	14.90	16.60
		SD	11.712	15.093
		Median	14.85	17.82
		Min.	-14.9	-20.8
		Max.	44.6	47.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 4.111
Summary of Absolute and Change from Baseline in the SF-12 Hybrid

Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	SF-12 Score	n	166	165
		Mean	55.86	53.43
		SD	10.152	12.438
		Median	58.54	55.57
		Min.	22.9	22.9
		Max.	70.4	70.4
	Change from Baseline	n	143	143
		Mean	16.79	13.44
		SD	12.481	14.155
		Median	17.82	11.88
		Min.	-11.9	-23.8
		Max.	44.6	44.6
Week 24	SF-12 Score	n	192	183
		Mean	54.04	54.15
		SD	10.781	11.650
		Median	55.57	58.54
		Min.	22.9	22.9
		Max.	70.4	70.4
	Change from Baseline	n	165	160
		Mean	14.06	13.99
		SD	13.591	13.677
		Median	11.89	14.85
		Min.	-26.7	-23.8
		Max.	44.6	47.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Physical Functioning (0-100 score)
Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	221	219
LS Mean (SE)	82.01 (1.641)	83.19 (1.634)
95% C.I.	(78.78, 85.23)	(79.98, 86.40)
LS Mean Change from Baseline (SE)	24.36 (1.641)	25.54 (1.634)
95% C.I.	(21.13, 27.58)	(22.33, 28.75)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.18 (2.318)
95% C.I.		(-3.37, 5.74)
p-value		0.611
Corrected Hedge’s g (SE) [3]		0.05 (0.095)
95% C.I.		(-0.14, 0.24)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Physical Functioning (0-100 score)
Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	228	230
LS Mean (SE)	84.21 (1.534)	83.31 (1.521)
95% C.I.	(81.19, 87.22)	(80.33, 86.30)
LS Mean Change from Baseline (SE)	26.56 (1.534)	25.66 (1.521)
95% C.I.	(23.54, 29.57)	(22.68, 28.65)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.89 (2.161)
95% C.I.		(-5.14, 3.35)
p-value		0.680
Corrected Hedge’s g (SE) [3]		-0.04 (0.093)
95% C.I.		(-0.22, 0.14)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Physical Functioning (0-100 score)
Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	60	56
LS Mean (SE)	85.54 (2.773)	88.09 (2.880)
95% C.I.	(80.06, 91.03)	(82.40, 93.79)
LS Mean Change from Baseline (SE)	27.89 (2.773)	30.44 (2.880)
95% C.I.	(22.41, 33.38)	(24.75, 36.14)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		2.55 (4.008)
95% C.I.		(-5.38, 10.48)
p-value		0.526
Corrected Hedge’s g (SE) [3]		0.12 (0.186)
95% C.I.		(-0.25, 0.48)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Physical Functioning (0-100 score)
Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	144	143
LS Mean (SE)	85.37 (1.935)	83.61 (1.938)
95% C.I.	(81.56, 89.17)	(79.80, 87.42)
LS Mean Change from Baseline (SE)	27.72 (1.935)	25.96 (1.938)
95% C.I.	(23.91, 31.52)	(22.15, 29.77)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.76 (2.741)
95% C.I.		(-7.15, 3.63)
p-value		0.522
Corrected Hedge’s g (SE) [3]		-0.08 (0.118)
95% C.I.		(-0.31, 0.16)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Physical Functioning (0-100 score)
Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	164	159
LS Mean (SE)	85.45 (1.739)	85.88 (1.748)
95% C.I.	(82.03, 88.87)	(82.44, 89.32)
LS Mean Change from Baseline (SE)	27.80 (1.739)	28.23 (1.748)
95% C.I.	(24.38, 31.22)	(24.79, 31.67)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.43 (2.468)
95% C.I.		(-4.42, 5.28)
p-value		0.862
Corrected Hedge’s g (SE) [3]		0.02 (0.111)
95% C.I.		(-0.20, 0.24)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Role Physical (0-100 score)
Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	221	219
LS Mean (SE)	80.90 (1.475)	83.81 (1.473)
95% C.I.	(78.00, 83.80)	(80.92, 86.71)
LS Mean Change from Baseline (SE)	28.75 (1.475)	31.66 (1.473)
95% C.I.	(25.85, 31.65)	(28.77, 34.56)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		2.91 (2.089)
95% C.I.		(-1.19, 7.02)
p-value		0.165
Corrected Hedge’s g (SE) [3]		0.13 (0.095)
95% C.I.		(-0.05, 0.32)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Role Physical (0-100 score)
Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	228	230
LS Mean (SE)	81.74 (1.498)	82.02 (1.487)
95% C.I.	(78.80, 84.69)	(79.10, 84.94)
LS Mean Change from Baseline (SE)	29.59 (1.498)	29.87 (1.487)
95% C.I.	(26.65, 32.54)	(26.95, 32.79)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.28 (2.113)
95% C.I.		(-3.88, 4.43)
p-value		0.897
Corrected Hedge’s g (SE) [3]		0.01 (0.093)
95% C.I.		(-0.17, 0.20)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Role Physical (0-100 score)
Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	60	56
LS Mean (SE)	86.41 (2.400)	88.12 (2.497)
95% C.I.	(81.66, 91.15)	(83.18, 93.06)
LS Mean Change from Baseline (SE)	34.26 (2.400)	35.97 (2.497)
95% C.I.	(29.51, 39.00)	(31.03, 40.90)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.71 (3.457)
95% C.I.		(-5.13, 8.55)
p-value		0.622
Corrected Hedge’s g (SE) [3]		0.09 (0.186)
95% C.I.		(-0.27, 0.46)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Role Physical (0-100 score)
Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	144	142
LS Mean (SE)	85.46 (1.776)	84.23 (1.787)
95% C.I.	(81.97, 88.95)	(80.71, 87.74)
LS Mean Change from Baseline (SE)	33.31 (1.776)	32.08 (1.787)
95% C.I.	(29.81, 36.80)	(28.56, 35.59)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.23 (2.523)
95% C.I.		(-6.20, 3.73)
p-value		0.626
Corrected Hedge’s g (SE) [3]		-0.06 (0.118)
95% C.I.		(-0.29, 0.17)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Role Physical (0-100 score)
Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	163	159
LS Mean (SE)	85.43 (1.564)	86.75 (1.581)
95% C.I.	(82.36, 88.51)	(83.64, 89.86)
LS Mean Change from Baseline (SE)	33.28 (1.564)	34.60 (1.581)
95% C.I.	(30.21, 36.36)	(31.49, 37.70)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.32 (2.226)
95% C.I.		(-3.06, 5.69)
p-value		0.555
Corrected Hedge’s g (SE) [3]		0.07 (0.111)
95% C.I.		(-0.15, 0.28)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Bodily Pain (0-100 score)
Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	308
n [2]	221	218
LS Mean (SE)	83.57 (1.593)	87.04 (1.600)
95% C.I.	(80.44, 86.70)	(83.90, 90.18)
LS Mean Change from Baseline (SE)	21.55 (1.593)	25.01 (1.600)
95% C.I.	(18.42, 24.68)	(21.87, 28.16)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		3.47 (2.258)
95% C.I.		(-0.97, 7.91)
p-value		0.126
Corrected Hedge’s g (SE) [3]		0.15 (0.096)
95% C.I.		(-0.04, 0.33)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Bodily Pain (0-100 score)
Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	308
n [2]	228	227
LS Mean (SE)	86.87 (1.453)	87.99 (1.452)
95% C.I.	(84.02, 89.73)	(85.14, 90.84)
LS Mean Change from Baseline (SE)	24.85 (1.453)	25.96 (1.452)
95% C.I.	(21.99, 27.70)	(23.11, 28.81)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.12 (2.054)
95% C.I.		(-2.92, 5.15)
p-value		0.587
Corrected Hedge’s g (SE) [3]		0.05 (0.094)
95% C.I.		(-0.13, 0.23)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Bodily Pain (0-100 score)
Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	308
n [2]	60	56
LS Mean (SE)	86.48 (2.488)	92.09 (2.568)
95% C.I.	(81.56, 91.41)	(87.01, 97.18)
LS Mean Change from Baseline (SE)	24.46 (2.488)	30.07 (2.568)
95% C.I.	(19.53, 29.38)	(24.99, 35.15)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		5.61 (3.578)
95% C.I.		(-1.47, 12.69)
p-value		0.120
Corrected Hedge’s g (SE) [3]		0.29 (0.187)
95% C.I.		(-0.08, 0.66)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Bodily Pain (0-100 score)
Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	308
n [2]	142	141
LS Mean (SE)	87.80 (1.689)	87.62 (1.692)
95% C.I.	(84.48, 91.12)	(84.30, 90.95)
LS Mean Change from Baseline (SE)	25.77 (1.689)	25.60 (1.692)
95% C.I.	(22.45, 29.10)	(22.27, 28.93)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.18 (2.388)
95% C.I.		(-4.87, 4.52)
p-value		0.942
Corrected Hedge’s g (SE) [3]		-0.01 (0.119)
95% C.I.		(-0.24, 0.22)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Bodily Pain (0-100 score)
Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	308
n [2]	162	156
LS Mean (SE)	88.10 (1.621)	87.01 (1.643)
95% C.I.	(84.91, 91.29)	(83.78, 90.24)
LS Mean Change from Baseline (SE)	26.07 (1.621)	24.98 (1.643)
95% C.I.	(22.89, 29.26)	(21.75, 28.21)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.09 (2.307)
95% C.I.		(-5.63, 3.44)
p-value		0.637
Corrected Hedge’s g (SE) [3]		-0.05 (0.112)
95% C.I.		(-0.27, 0.17)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: General Health (0-100 score)
Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	298	312
n [2]	221	218
LS Mean (SE)	72.40 (1.389)	72.19 (1.390)
95% C.I.	(69.67, 75.13)	(69.46, 74.92)
LS Mean Change from Baseline (SE)	17.57 (1.389)	17.36 (1.390)
95% C.I.	(14.85, 20.30)	(14.63, 20.09)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.21 (1.965)
95% C.I.		(-4.07, 3.65)
p-value		0.914
Corrected Hedge’s g (SE) [3]		-0.01 (0.095)
95% C.I.		(-0.20, 0.18)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: General Health (0-100 score)
Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	298	312
n [2]	226	230
LS Mean (SE)	71.90 (1.397)	72.46 (1.381)
95% C.I.	(69.16, 74.64)	(69.75, 75.17)
LS Mean Change from Baseline (SE)	17.07 (1.397)	17.63 (1.381)
95% C.I.	(14.33, 19.82)	(14.92, 20.35)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.56 (1.964)
95% C.I.		(-3.30, 4.42)
p-value		0.775
Corrected Hedge’s g (SE) [3]		0.03 (0.094)
95% C.I.		(-0.16, 0.21)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: General Health (0-100 score)
Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	298	312
n [2]	60	56
LS Mean (SE)	71.23 (2.581)	77.18 (2.679)
95% C.I.	(66.12, 76.34)	(71.87, 82.48)
LS Mean Change from Baseline (SE)	16.40 (2.581)	22.35 (2.679)
95% C.I.	(11.29, 21.51)	(17.04, 27.65)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		5.95 (3.712)
95% C.I.		(-1.40, 13.29)
p-value		0.112
Corrected Hedge’s g (SE) [3]		0.29 (0.187)
95% C.I.		(-0.07, 0.66)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: General Health (0-100 score)
Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	298	312
n [2]	143	142
LS Mean (SE)	74.32 (1.565)	74.01 (1.555)
95% C.I.	(71.24, 77.40)	(70.95, 77.07)
LS Mean Change from Baseline (SE)	19.49 (1.565)	19.18 (1.555)
95% C.I.	(16.42, 22.57)	(16.12, 22.24)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.31 (2.204)
95% C.I.		(-4.65, 4.02)
p-value		0.888
Corrected Hedge’s g (SE) [3]		-0.02 (0.118)
95% C.I.		(-0.25, 0.22)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: General Health (0-100 score)
Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	298	312
n [2]	161	159
LS Mean (SE)	73.43 (1.486)	73.93 (1.484)
95% C.I.	(70.51, 76.35)	(71.01, 76.85)
LS Mean Change from Baseline (SE)	18.60 (1.486)	19.10 (1.484)
95% C.I.	(15.68, 21.52)	(16.18, 22.02)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.50 (2.098)
95% C.I.		(-3.63, 4.62)
p-value		0.813
Corrected Hedge’s g (SE) [3]		0.03 (0.112)
95% C.I.		(-0.19, 0.25)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Vitality (0-100 score)
Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	310
n [2]	221	219
LS Mean (SE)	64.83 (1.915)	63.84 (1.919)
95% C.I.	(61.06, 68.59)	(60.07, 67.61)
LS Mean Change from Baseline (SE)	30.34 (1.915)	29.36 (1.919)
95% C.I.	(26.58, 34.11)	(25.59, 33.13)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.98 (2.711)
95% C.I.		(-6.31, 4.34)
p-value		0.718
Corrected Hedge’s g (SE) [3]		-0.03 (0.095)
95% C.I.		(-0.22, 0.15)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Vitality (0-100 score)
Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	310
n [2]	228	229
LS Mean (SE)	60.09 (1.985)	63.22 (1.978)
95% C.I.	(56.19, 63.99)	(59.34, 67.11)
LS Mean Change from Baseline (SE)	25.61 (1.985)	28.74 (1.978)
95% C.I.	(21.71, 29.51)	(24.85, 32.63)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		3.13 (2.802)
95% C.I.		(-2.37, 8.64)
p-value		0.265
Corrected Hedge’s g (SE) [3]		0.10 (0.094)
95% C.I.		(-0.08, 0.29)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Vitality (0-100 score)
Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	310
n [2]	60	55
LS Mean (SE)	65.32 (3.554)	71.44 (3.692)
95% C.I.	(58.29, 72.35)	(64.13, 78.74)
LS Mean Change from Baseline (SE)	30.84 (3.554)	36.95 (3.692)
95% C.I.	(23.80, 37.87)	(29.65, 44.26)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		6.12 (5.124)
95% C.I.		(-4.03, 16.26)
p-value		0.235
Corrected Hedge’s g (SE) [3]		0.22 (0.187)
95% C.I.		(-0.15, 0.59)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Vitality (0-100 score)
Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	310
n [2]	142	142
LS Mean (SE)	63.14 (2.388)	59.75 (2.378)
95% C.I.	(58.44, 67.83)	(55.07, 64.43)
LS Mean Change from Baseline (SE)	28.65 (2.388)	25.27 (2.378)
95% C.I.	(23.96, 33.35)	(20.59, 29.95)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-3.39 (3.341)
95% C.I.		(-9.96, 3.19)
p-value		0.312
Corrected Hedge’s g (SE) [3]		-0.12 (0.119)
95% C.I.		(-0.35, 0.11)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Vitality (0-100 score)
Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	310
n [2]	164	155
LS Mean (SE)	58.87 (2.222)	59.87 (2.268)
95% C.I.	(54.50, 63.24)	(55.41, 64.33)
LS Mean Change from Baseline (SE)	24.39 (2.222)	25.38 (2.268)
95% C.I.	(20.02, 28.76)	(20.92, 29.84)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.99 (3.160)
95% C.I.		(-5.22, 7.21)
p-value		0.754
Corrected Hedge’s g (SE) [3]		0.03 (0.112)
95% C.I.		(-0.18, 0.25)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Social Functioning (0-100 score)
Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	221	219
LS Mean (SE)	83.08 (1.452)	87.20 (1.453)
95% C.I.	(80.23, 85.94)	(84.35, 90.06)
LS Mean Change from Baseline (SE)	35.79 (1.452)	39.91 (1.453)
95% C.I.	(32.93, 38.64)	(37.05, 42.76)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		4.12 (2.055)
95% C.I.		(0.08, 8.16)
p-value		0.046
Corrected Hedge’s g (SE) [3]		0.19 (0.096)
95% C.I.		(0.00, 0.38)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Social Functioning (0-100 score)
Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	226	230
LS Mean (SE)	83.51 (1.525)	88.06 (1.510)
95% C.I.	(80.51, 86.51)	(85.09, 91.03)
LS Mean Change from Baseline (SE)	36.21 (1.525)	40.77 (1.510)
95% C.I.	(33.22, 39.21)	(37.80, 43.73)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		4.55 (2.147)
95% C.I.		(0.33, 8.77)
p-value		0.035
Corrected Hedge’s g (SE) [3]		0.20 (0.094)
95% C.I.		(0.01, 0.38)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Social Functioning (0-100 score)
Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	59	56
LS Mean (SE)	92.37 (2.030)	92.83 (2.085)
95% C.I.	(88.35, 96.38)	(88.70, 96.95)
LS Mean Change from Baseline (SE)	45.07 (2.030)	45.53 (2.085)
95% C.I.	(41.06, 49.09)	(41.41, 49.66)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.46 (2.911)
95% C.I.		(-5.30, 6.22)
p-value		0.875
Corrected Hedge’s g (SE) [3]		0.03 (0.187)
95% C.I.		(-0.34, 0.39)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Social Functioning (0-100 score)
Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	143	142
LS Mean (SE)	92.68 (1.433)	90.18 (1.437)
95% C.I.	(89.86, 95.50)	(87.36, 93.01)
LS Mean Change from Baseline (SE)	45.39 (1.433)	42.89 (1.437)
95% C.I.	(42.57, 48.21)	(40.06, 45.71)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-2.50 (2.030)
95% C.I.		(-6.49, 1.49)
p-value		0.220
Corrected Hedge’s g (SE) [3]		-0.15 (0.119)
95% C.I.		(-0.38, 0.09)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Social Functioning (0-100 score)
Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	162	157
LS Mean (SE)	91.31 (1.353)	90.77 (1.369)
95% C.I.	(88.65, 93.98)	(88.07, 93.46)
LS Mean Change from Baseline (SE)	44.02 (1.353)	43.47 (1.369)
95% C.I.	(41.36, 46.68)	(40.78, 46.16)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.55 (1.921)
95% C.I.		(-4.33, 3.23)
p-value		0.776
Corrected Hedge’s g (SE) [3]		-0.03 (0.112)
95% C.I.		(-0.25, 0.19)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Role Emotional (0-100 score)
Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	221	219
LS Mean (SE)	85.37 (1.262)	88.99 (1.257)
95% C.I.	(82.89, 87.85)	(86.52, 91.46)
LS Mean Change from Baseline (SE)	18.10 (1.262)	21.72 (1.257)
95% C.I.	(15.62, 20.58)	(19.25, 24.19)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		3.62 (1.786)
95% C.I.		(0.11, 7.13)
p-value		0.044
Corrected Hedge’s g (SE) [3]		0.19 (0.096)
95% C.I.		(0.01, 0.38)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Role Emotional (0-100 score)
Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	228	230
LS Mean (SE)	83.93 (1.331)	87.46 (1.323)
95% C.I.	(81.32, 86.55)	(84.86, 90.06)
LS Mean Change from Baseline (SE)	16.66 (1.331)	20.19 (1.323)
95% C.I.	(14.05, 19.28)	(17.59, 22.79)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		3.53 (1.879)
95% C.I.		(-0.16, 7.22)
p-value		0.061
Corrected Hedge’s g (SE) [3]		0.18 (0.094)
95% C.I.		(-0.01, 0.36)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Role Emotional (0-100 score)
Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	60	56
LS Mean (SE)	90.35 (1.866)	93.56 (1.926)
95% C.I.	(86.66, 94.04)	(89.75, 97.37)
LS Mean Change from Baseline (SE)	23.08 (1.866)	26.29 (1.926)
95% C.I.	(19.39, 26.77)	(22.48, 30.10)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		3.21 (2.684)
95% C.I.		(-2.10, 8.52)
p-value		0.235
Corrected Hedge’s g (SE) [3]		0.22 (0.186)
95% C.I.		(-0.14, 0.59)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Role Emotional (0-100 score)
Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	144	143
LS Mean (SE)	90.27 (1.340)	89.31 (1.346)
95% C.I.	(87.63, 92.90)	(86.66, 91.96)
LS Mean Change from Baseline (SE)	22.99 (1.340)	22.04 (1.346)
95% C.I.	(20.36, 25.63)	(19.39, 24.69)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.96 (1.896)
95% C.I.		(-4.69, 2.77)
p-value		0.615
Corrected Hedge’s g (SE) [3]		-0.06 (0.118)
95% C.I.		(-0.29, 0.17)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Role Emotional (0-100 score)
Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	164	159
LS Mean (SE)	90.99 (1.138)	89.81 (1.159)
95% C.I.	(88.75, 93.23)	(87.53, 92.08)
LS Mean Change from Baseline (SE)	23.72 (1.138)	22.53 (1.159)
95% C.I.	(21.48, 25.95)	(20.26, 24.81)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.18 (1.621)
95% C.I.		(-4.37, 2.00)
p-value		0.467
Corrected Hedge’s g (SE) [3]		-0.08 (0.111)
95% C.I.		(-0.30, 0.14)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Mental Health (0-100 score)
Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	221	219
LS Mean (SE)	76.44 (1.414)	77.27 (1.413)
95% C.I.	(73.66, 79.22)	(74.50, 80.05)
LS Mean Change from Baseline (SE)	17.24 (1.414)	18.07 (1.413)
95% C.I.	(14.46, 20.02)	(15.30, 20.85)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.83 (1.999)
95% C.I.		(-3.09, 4.76)
p-value		0.677
Corrected Hedge’s g (SE) [3]		0.04 (0.095)
95% C.I.		(-0.15, 0.23)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Mental Health (0-100 score)
Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	228	230
LS Mean (SE)	74.89 (1.411)	76.86 (1.404)
95% C.I.	(72.12, 77.66)	(74.10, 79.61)
LS Mean Change from Baseline (SE)	15.69 (1.411)	17.66 (1.404)
95% C.I.	(12.92, 18.46)	(14.90, 20.41)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.97 (1.991)
95% C.I.		(-1.95, 5.88)
p-value		0.324
Corrected Hedge’s g (SE) [3]		0.09 (0.094)
95% C.I.		(-0.09, 0.28)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Mental Health (0-100 score)
Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	60	56
LS Mean (SE)	77.92 (2.181)	82.25 (2.245)
95% C.I.	(73.60, 82.23)	(77.81, 86.70)
LS Mean Change from Baseline (SE)	18.72 (2.181)	23.05 (2.245)
95% C.I.	(14.40, 23.03)	(18.61, 27.50)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		4.34 (3.130)
95% C.I.		(-1.86, 10.53)
p-value		0.169
Corrected Hedge’s g (SE) [3]		0.26 (0.187)
95% C.I.		(-0.11, 0.62)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Mental Health (0-100 score)
Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	143	142
LS Mean (SE)	83.05 (1.494)	79.88 (1.496)
95% C.I.	(80.11, 85.98)	(76.94, 82.82)
LS Mean Change from Baseline (SE)	23.85 (1.494)	20.68 (1.496)
95% C.I.	(20.91, 26.78)	(17.74, 23.62)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-3.17 (2.111)
95% C.I.		(-7.32, 0.99)
p-value		0.135
Corrected Hedge’s g (SE) [3]		-0.18 (0.119)
95% C.I.		(-0.41, 0.06)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Mental Health (0-100 score)
Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	165	159
LS Mean (SE)	79.19 (1.413)	80.24 (1.434)
95% C.I.	(76.41, 81.96)	(77.42, 83.06)
LS Mean Change from Baseline (SE)	19.98 (1.413)	21.04 (1.434)
95% C.I.	(17.21, 22.76)	(18.22, 23.86)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.06 (2.009)
95% C.I.		(-2.89, 5.01)
p-value		0.599
Corrected Hedge’s g (SE) [3]		0.06 (0.111)
95% C.I.		(-0.16, 0.28)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Physical Component Summary
Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	310
n [2]	221	219
LS Mean (SE)	51.50 (0.502)	52.03 (0.502)
95% C.I.	(50.51, 52.49)	(51.04, 53.01)
LS Mean Change from Baseline (SE)	7.91 (0.502)	8.44 (0.502)
95% C.I.	(6.93, 8.90)	(7.45, 9.42)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.53 (0.710)
95% C.I.		(-0.87, 1.92)
p-value		0.460
Corrected Hedge’s g (SE) [3]		0.07 (0.095)
95% C.I.		(-0.12, 0.26)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Physical Component Summary
Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	310
n [2]	228	229
LS Mean (SE)	52.48 (0.457)	52.18 (0.454)
95% C.I.	(51.58, 53.38)	(51.29, 53.07)
LS Mean Change from Baseline (SE)	8.89 (0.457)	8.59 (0.454)
95% C.I.	(8.00, 9.79)	(7.70, 9.49)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.30 (0.644)
95% C.I.		(-1.57, 0.97)
p-value		0.642
Corrected Hedge’s g (SE) [3]		-0.04 (0.094)
95% C.I.		(-0.23, 0.14)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Physical Component Summary
Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	310
n [2]	60	56
LS Mean (SE)	52.26 (0.791)	53.40 (0.825)
95% C.I.	(50.70, 53.83)	(51.77, 55.03)
LS Mean Change from Baseline (SE)	8.67 (0.791)	9.81 (0.825)
95% C.I.	(7.11, 10.24)	(8.18, 11.44)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.14 (1.142)
95% C.I.		(-1.12, 3.39)
p-value		0.322
Corrected Hedge’s g (SE) [3]		0.18 (0.186)
95% C.I.		(-0.18, 0.55)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Physical Component Summary
Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	310
n [2]	142	142
LS Mean (SE)	52.12 (0.548)	52.00 (0.547)
95% C.I.	(51.04, 53.20)	(50.93, 53.08)
LS Mean Change from Baseline (SE)	8.53 (0.548)	8.41 (0.547)
95% C.I.	(7.45, 9.61)	(7.34, 9.49)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.12 (0.774)
95% C.I.		(-1.64, 1.40)
p-value		0.878
Corrected Hedge’s g (SE) [3]		-0.02 (0.119)
95% C.I.		(-0.25, 0.21)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Physical Component Summary
Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	310
n [2]	163	157
LS Mean (SE)	52.41 (0.487)	52.49 (0.490)
95% C.I.	(51.45, 53.37)	(51.53, 53.46)
LS Mean Change from Baseline (SE)	8.82 (0.487)	8.91 (0.490)
95% C.I.	(7.86, 9.78)	(7.94, 9.87)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.09 (0.691)
95% C.I.		(-1.27, 1.44)
p-value		0.902
Corrected Hedge’s g (SE) [3]		0.01 (0.112)
95% C.I.		(-0.21, 0.23)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Mental Component Summary
Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	310
n [2]	221	219
LS Mean (SE)	52.44 (0.565)	53.28 (0.564)
95% C.I.	(51.33, 53.55)	(52.17, 54.39)
LS Mean Change from Baseline (SE)	9.51 (0.565)	10.35 (0.564)
95% C.I.	(8.40, 10.62)	(9.24, 11.46)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.84 (0.799)
95% C.I.		(-0.73, 2.41)
p-value		0.296
Corrected Hedge’s g (SE) [3]		0.10 (0.095)
95% C.I.		(-0.09, 0.29)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Mental Component Summary
Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	310
n [2]	228	229
LS Mean (SE)	51.23 (0.594)	52.92 (0.592)
95% C.I.	(50.06, 52.39)	(51.75, 54.08)
LS Mean Change from Baseline (SE)	8.30 (0.594)	9.99 (0.592)
95% C.I.	(7.13, 9.47)	(8.83, 11.15)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.69 (0.840)
95% C.I.		(0.04, 3.34)
p-value		0.045
Corrected Hedge’s g (SE) [3]		0.19 (0.094)
95% C.I.		(0.00, 0.37)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Mental Component Summary
Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	310
n [2]	60	56
LS Mean (SE)	53.82 (0.907)	55.65 (0.934)
95% C.I.	(52.02, 55.61)	(53.81, 57.50)
LS Mean Change from Baseline (SE)	10.89 (0.907)	12.73 (0.934)
95% C.I.	(9.10, 12.68)	(10.88, 14.58)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.84 (1.302)
95% C.I.		(-0.74, 4.41)
p-value		0.161
Corrected Hedge’s g (SE) [3]		0.26 (0.187)
95% C.I.		(-0.11, 0.63)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Mental Component Summary
Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	310
n [2]	142	142
LS Mean (SE)	54.98 (0.600)	53.84 (0.599)
95% C.I.	(53.80, 56.16)	(52.66, 55.02)
LS Mean Change from Baseline (SE)	12.05 (0.600)	10.91 (0.599)
95% C.I.	(10.87, 13.23)	(9.74, 12.09)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.14 (0.847)
95% C.I.		(-2.81, 0.53)
p-value		0.179
Corrected Hedge’s g (SE) [3]		-0.16 (0.119)
95% C.I.		(-0.39, 0.07)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Mental Component Summary
Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	310
n [2]	163	157
LS Mean (SE)	53.93 (0.568)	53.87 (0.576)
95% C.I.	(52.81, 55.04)	(52.74, 55.00)
LS Mean Change from Baseline (SE)	11.00 (0.568)	10.94 (0.576)
95% C.I.	(9.88, 12.12)	(9.81, 12.07)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.06 (0.808)
95% C.I.		(-1.65, 1.53)
p-value		0.943
Corrected Hedge’s g (SE) [3]		-0.01 (0.112)
95% C.I.		(-0.23, 0.21)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Health Utility Index
Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	308
n [2]	221	217
LS Mean (SE)	0.80 (0.009)	0.83 (0.009)
95% C.I.	(0.78, 0.82)	(0.81, 0.84)
LS Mean Change from Baseline (SE)	0.16 (0.009)	0.18 (0.009)
95% C.I.	(0.14, 0.18)	(0.16, 0.20)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.02 (0.013)
95% C.I.		(0.00, 0.05)
p-value		0.082
Corrected Hedge’s g (SE) [3]		0.17 (0.096)
95% C.I.		(-0.02, 0.35)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Health Utility Index
Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	308
n [2]	224	227
LS Mean (SE)	0.80 (0.009)	0.83 (0.009)
95% C.I.	(0.79, 0.82)	(0.81, 0.85)
LS Mean Change from Baseline (SE)	0.16 (0.009)	0.19 (0.009)
95% C.I.	(0.14, 0.18)	(0.17, 0.20)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.03 (0.013)
95% C.I.		(0.00, 0.05)
p-value		0.035
Corrected Hedge’s g (SE) [3]		0.20 (0.094)
95% C.I.		(0.01, 0.38)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Health Utility Index
Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	308
n [2]	59	53
LS Mean (SE)	0.84 (0.015)	0.88 (0.016)
95% C.I.	(0.81, 0.87)	(0.85, 0.91)
LS Mean Change from Baseline (SE)	0.20 (0.015)	0.23 (0.016)
95% C.I.	(0.17, 0.23)	(0.20, 0.26)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.04 (0.022)
95% C.I.		(-0.01, 0.08)
p-value		0.109
Corrected Hedge’s g (SE) [3]		0.30 (0.190)
95% C.I.		(-0.07, 0.68)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Health Utility Index
Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	308
n [2]	140	136
LS Mean (SE)	0.84 (0.010)	0.84 (0.010)
95% C.I.	(0.82, 0.86)	(0.82, 0.86)
LS Mean Change from Baseline (SE)	0.20 (0.010)	0.20 (0.010)
95% C.I.	(0.18, 0.22)	(0.18, 0.21)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.00 (0.014)
95% C.I.		(-0.03, 0.03)
p-value		0.942
Corrected Hedge’s g (SE) [3]		-0.01 (0.120)
95% C.I.		(-0.24, 0.23)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Health Utility Index
Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	308
n [2]	154	149
LS Mean (SE)	0.83 (0.009)	0.84 (0.009)
95% C.I.	(0.81, 0.84)	(0.82, 0.86)
LS Mean Change from Baseline (SE)	0.18 (0.009)	0.19 (0.009)
95% C.I.	(0.16, 0.20)	(0.18, 0.21)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.01 (0.013)
95% C.I.		(-0.01, 0.04)
p-value		0.336
Corrected Hedge’s g (SE) [3]		0.11 (0.115)
95% C.I.		(-0.11, 0.34)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Role Physical Enhanced (0-100 score)
Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	221	219
LS Mean (SE)	81.38 (1.356)	84.96 (1.351)
95% C.I.	(78.72, 84.05)	(82.30, 87.61)
LS Mean Change from Baseline (SE)	31.79 (1.356)	35.37 (1.351)
95% C.I.	(29.13, 34.46)	(32.71, 38.02)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		3.57 (1.915)
95% C.I.		(-0.19, 7.34)
p-value		0.063
Corrected Hedge’s g (SE) [3]		0.18 (0.096)
95% C.I.		(-0.01, 0.37)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Role Physical Enhanced (0-100 score)
Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	228	230
LS Mean (SE)	82.36 (1.351)	83.93 (1.339)
95% C.I.	(79.71, 85.02)	(81.30, 86.56)
LS Mean Change from Baseline (SE)	32.77 (1.351)	34.34 (1.339)
95% C.I.	(30.12, 35.43)	(31.71, 36.97)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.57 (1.903)
95% C.I.		(-2.17, 5.31)
p-value		0.410
Corrected Hedge’s g (SE) [3]		0.08 (0.093)
95% C.I.		(-0.11, 0.26)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Role Physical Enhanced (0-100 score)
Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	60	56
LS Mean (SE)	86.22 (2.110)	88.25 (2.188)
95% C.I.	(82.05, 90.39)	(83.92, 92.57)
LS Mean Change from Baseline (SE)	36.63 (2.110)	38.66 (2.188)
95% C.I.	(32.46, 40.80)	(34.33, 42.98)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		2.02 (3.032)
95% C.I.		(-3.97, 8.02)
p-value		0.506
Corrected Hedge’s g (SE) [3]		0.12 (0.186)
95% C.I.		(-0.24, 0.49)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Role Physical Enhanced (0-100 score)
Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	144	143
LS Mean (SE)	86.07 (1.521)	84.85 (1.522)
95% C.I.	(83.08, 89.06)	(81.86, 87.84)
LS Mean Change from Baseline (SE)	36.48 (1.521)	35.26 (1.522)
95% C.I.	(33.49, 39.47)	(32.27, 38.25)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.22 (2.153)
95% C.I.		(-5.45, 3.01)
p-value		0.572
Corrected Hedge’s g (SE) [3]		-0.07 (0.118)
95% C.I.		(-0.30, 0.16)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Role Physical Enhanced (0-100 score)
Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	164	160
LS Mean (SE)	86.53 (1.408)	86.85 (1.417)
95% C.I.	(83.77, 89.30)	(84.06, 89.63)
LS Mean Change from Baseline (SE)	36.94 (1.408)	37.26 (1.417)
95% C.I.	(34.17, 39.71)	(34.47, 40.04)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.32 (1.997)
95% C.I.		(-3.61, 4.24)
p-value		0.875
Corrected Hedge’s g (SE) [3]		0.02 (0.111)
95% C.I.		(-0.20, 0.24)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Vitality Enhanced (0-100 score)
Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	221	219
LS Mean (SE)	70.60 (1.465)	69.46 (1.464)
95% C.I.	(67.72, 73.48)	(66.59, 72.34)
LS Mean Change from Baseline (SE)	31.42 (1.465)	30.28 (1.464)
95% C.I.	(28.54, 34.30)	(27.41, 33.16)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.13 (2.072)
95% C.I.		(-5.20, 2.94)
p-value		0.585
Corrected Hedge’s g (SE) [3]		-0.05 (0.095)
95% C.I.		(-0.24, 0.13)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Vitality Enhanced (0-100 score)
Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	228	230
LS Mean (SE)	67.18 (1.429)	70.45 (1.419)
95% C.I.	(64.37, 69.99)	(67.66, 73.24)
LS Mean Change from Baseline (SE)	28.00 (1.429)	31.27 (1.419)
95% C.I.	(25.19, 30.81)	(28.48, 34.06)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		3.27 (2.014)
95% C.I.		(-0.69, 7.23)
p-value		0.105
Corrected Hedge’s g (SE) [3]		0.15 (0.094)
95% C.I.		(-0.03, 0.33)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Vitality Enhanced (0-100 score)
Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	60	56
LS Mean (SE)	70.43 (2.589)	76.65 (2.662)
95% C.I.	(65.31, 75.55)	(71.39, 81.92)
LS Mean Change from Baseline (SE)	31.25 (2.589)	37.47 (2.662)
95% C.I.	(26.13, 36.37)	(32.21, 42.74)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		6.23 (3.714)
95% C.I.		(-1.12, 13.57)
p-value		0.096
Corrected Hedge’s g (SE) [3]		0.31 (0.187)
95% C.I.		(-0.06, 0.68)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Vitality Enhanced (0-100 score)
Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	143	143
LS Mean (SE)	72.16 (1.723)	68.72 (1.711)
95% C.I.	(68.77, 75.55)	(65.36, 72.09)
LS Mean Change from Baseline (SE)	32.98 (1.723)	29.54 (1.711)
95% C.I.	(29.59, 36.37)	(26.18, 32.91)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-3.44 (2.419)
95% C.I.		(-8.19, 1.32)
p-value		0.157
Corrected Hedge’s g (SE) [3]		-0.17 (0.118)
95% C.I.		(-0.40, 0.07)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 34.4
Analysis of Change from Baseline in SF-12 Hybrid at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Vitality Enhanced (0-100 score)
Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	299	311
n [2]	165	160
LS Mean (SE)	67.77 (1.621)	69.31 (1.629)
95% C.I.	(64.58, 70.96)	(66.11, 72.52)
LS Mean Change from Baseline (SE)	28.59 (1.621)	30.13 (1.629)
95% C.I.	(25.40, 31.78)	(26.93, 33.34)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.54 (2.294)
95% C.I.		(-2.97, 6.05)
p-value		0.502
Corrected Hedge’s g (SE) [3]		0.07 (0.111)
95% C.I.		(-0.14, 0.29)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 34.5
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - GBA Approach

Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	114 (22%)	113 (21%)
Non-responder	107 (20%)	106 (20%)
Missing [1]	308 (58%)	309 (59%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.01
95% C.I.		(0.75, 1.35)
p-value		0.954
Inverse Relative Risk [3]		1.01
95% C.I.		(0.80, 1.27)
p-value		0.954
Risk Difference (%) [4]		0.15
95% C.I.		(-4.80, 5.10)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=9.9 (GBA Approach).

PPD

Population: Intent-to-Treat

Table 34.5
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - GBA Approach

Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	100 (19%)	106 (20%)
Non-responder	128 (24%)	123 (23%)
Missing [1]	301 (57%)	299 (57%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.93
95% C.I.		(0.68, 1.26)
p-value		0.631
Inverse Relative Risk [3]		0.94
95% C.I.		(0.74, 1.20)
p-value		0.631
Risk Difference (%) [4]		-1.17
95% C.I.		(-5.95, 3.60)
p-value		0.643

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=9.9 (GBA Approach).

PPD

Population: Intent-to-Treat

Table 34.5
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - GBA Approach

Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	30 (6%)	32 (6%)
Non-responder	30 (6%)	24 (5%)
Missing [1]	469 (89%)	472 (89%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.93
95% C.I.		(0.56, 1.56)
p-value		0.788
Inverse Relative Risk [3]		0.94
95% C.I.		(0.58, 1.52)
p-value		0.788
Risk Difference (%) [4]		-0.39
95% C.I.		(-3.22, 2.44)
p-value		0.796

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=9.9 (GBA Approach).

PPD

Population: Intent-to-Treat

Table 34.5
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - GBA Approach

Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	77 (15%)	64 (12%)
Non-responder	65 (12%)	78 (15%)
Missing [1]	387 (73%)	386 (73%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.24
95% C.I.		(0.87, 1.76)
p-value		0.246
Inverse Relative Risk [3]		1.20
95% C.I.		(0.88, 1.64)
p-value		0.246
Risk Difference (%) [4]		2.43
95% C.I.		(-1.66, 6.53)
p-value		0.278

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=9.9 (GBA Approach).

PPD

Population: Intent-to-Treat

Table 34.5
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - GBA Approach

Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	80 (15%)	74 (14%)
Non-responder	83 (16%)	83 (16%)
Missing [1]	366 (69%)	371 (70%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.09
95% C.I.		(0.78, 1.54)
p-value		0.610
Inverse Relative Risk [3]		1.08
95% C.I.		(0.81, 1.45)
p-value		0.610
Risk Difference (%) [4]		1.11
95% C.I.		(-3.15, 5.36)
p-value		0.664

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=9.9 (GBA Approach).

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 34.6
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - GBA Approach

Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	97 (18%)	108 (20%)
Non-responder	124 (23%)	111 (21%)
Missing [1]	308 (58%)	309 (59%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.87
95% C.I.		(0.64, 1.18)
p-value		0.385
Inverse Relative Risk [3]		0.90
95% C.I.		(0.70, 1.15)
p-value		0.385
Risk Difference (%) [4]		-2.12
95% C.I.		(-6.88, 2.65)
p-value		0.394

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=8.7 (GBA Approach).

PPD

Population: Intent-to-Treat

Table 34.6
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - GBA Approach

Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	112 (21%)	114 (22%)
Non-responder	116 (22%)	115 (22%)
Missing [1]	301 (57%)	299 (57%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.98
95% C.I.		(0.73, 1.31)
p-value		0.869
Inverse Relative Risk [3]		0.98
95% C.I.		(0.78, 1.24)
p-value		0.869
Risk Difference (%) [4]		-0.42
95% C.I.		(-5.36, 4.52)
p-value		0.881

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=8.7 (GBA Approach).

PPD

Population: Intent-to-Treat

Table 34.6
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - GBA Approach

Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	23 (4%)	25 (5%)
Non-responder	37 (7%)	31 (6%)
Missing [1]	469 (89%)	472 (89%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.91
95% C.I.		(0.51, 1.63)
p-value		0.763
Inverse Relative Risk [3]		0.92
95% C.I.		(0.53, 1.60)
p-value		0.763
Risk Difference (%) [4]		-0.39
95% C.I.		(-2.90, 2.12)
p-value		0.771

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=8.7 (GBA Approach).

PPD

Population: Intent-to-Treat

Table 34.6
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - GBA Approach

Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	65 (12%)	61 (12%)
Non-responder	77 (15%)	81 (15%)
Missing [1]	387 (73%)	386 (73%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.07
95% C.I.		(0.74, 1.56)
p-value		0.713
Inverse Relative Risk [3]		1.06
95% C.I.		(0.77, 1.48)
p-value		0.713
Risk Difference (%) [4]		0.73
95% C.I.		(-3.17, 4.64)
p-value		0.776

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=8.7 (GBA Approach).

PPD

Population: Intent-to-Treat

Table 34.6
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - GBA Approach

Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	80 (15%)	74 (14%)
Non-responder	83 (16%)	83 (16%)
Missing [1]	366 (69%)	371 (70%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.09
95% C.I.		(0.78, 1.54)
p-value		0.610
Inverse Relative Risk [3]		1.08
95% C.I.		(0.81, 1.45)
p-value		0.610
Risk Difference (%) [4]		1.11
95% C.I.		(-3.15, 5.36)
p-value		0.664

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=8.7 (GBA Approach).

PPD

Population: Intent-to-Treat

Table 34.7
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - QualityMetric Approach

Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	134 (25%)	129 (24%)
Non-responder	87 (16%)	90 (17%)
Missing [1]	308 (58%)	309 (59%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.05
95% C.I.		(0.79, 1.39)
p-value		0.736
Inverse Relative Risk [3]		1.04
95% C.I.		(0.84, 1.28)
p-value		0.736
Risk Difference (%) [4]		0.90
95% C.I.		(-4.31, 6.11)
p-value		0.777

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

PPD

Population: Intent-to-Treat

Table 34.7
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - QualityMetric Approach

Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	120 (23%)	130 (25%)
Non-responder	108 (20%)	99 (19%)
Missing [1]	301 (57%)	299 (57%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.90
95% C.I.		(0.68, 1.19)
p-value		0.459
Inverse Relative Risk [3]		0.92
95% C.I.		(0.74, 1.14)
p-value		0.459
Risk Difference (%) [4]		-1.94
95% C.I.		(-7.06, 3.19)
p-value		0.470

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

PPD

Population: Intent-to-Treat

Table 34.7
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - QualityMetric Approach

Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	38 (7%)	36 (7%)
Non-responder	22 (4%)	20 (4%)
Missing [1]	469 (89%)	472 (89%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.06
95% C.I.		(0.66, 1.70)
p-value		0.817
Inverse Relative Risk [3]		1.05
95% C.I.		(0.68, 1.64)
p-value		0.817
Risk Difference (%) [4]		0.37
95% C.I.		(-2.71, 3.44)
p-value		0.905

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

PPD

Population: Intent-to-Treat

Table 34.7
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - QualityMetric Approach

Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	91 (17%)	84 (16%)
Non-responder	51 (10%)	58 (11%)
Missing [1]	387 (73%)	386 (73%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.10
95% C.I.		(0.79, 1.52)
p-value		0.572
Inverse Relative Risk [3]		1.08
95% C.I.		(0.82, 1.42)
p-value		0.572
Risk Difference (%) [4]		1.29
95% C.I.		(-3.19, 5.77)
p-value		0.620

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

PPD

Population: Intent-to-Treat

Table 34.7
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - QualityMetric Approach

Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	103 (19%)	97 (18%)
Non-responder	60 (11%)	60 (11%)
Missing [1]	366 (69%)	371 (70%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.07
95% C.I.		(0.79, 1.46)
p-value		0.649
Inverse Relative Risk [3]		1.06
95% C.I.		(0.83, 1.36)
p-value		0.649
Risk Difference (%) [4]		1.10
95% C.I.		(-3.62, 5.82)
p-value		0.695

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 34.8
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - QualityMetric Approach

Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	119 (22%)	127 (24%)
Non-responder	102 (19%)	92 (17%)
Missing [1]	308 (58%)	309 (59%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.92
95% C.I.		(0.69, 1.22)
p-value		0.550
Inverse Relative Risk [3]		0.94
95% C.I.		(0.75, 1.16)
p-value		0.550
Risk Difference (%) [4]		-1.56
95% C.I.		(-6.65, 3.54)
p-value		0.562

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Table 34.8
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - QualityMetric Approach

Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	131 (25%)	134 (25%)
Non-responder	97 (18%)	95 (18%)
Missing [1]	301 (57%)	299 (57%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.97
95% C.I.		(0.73, 1.28)
p-value		0.818
Inverse Relative Risk [3]		0.98
95% C.I.		(0.79, 1.20)
p-value		0.818
Risk Difference (%) [4]		-0.62
95% C.I.		(-5.84, 4.61)
p-value		0.832

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Population: Intent-to-Treat

Table 34.8
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - QualityMetric Approach

Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	28 (5%)	27 (5%)
Non-responder	32 (6%)	29 (5%)
Missing [1]	469 (89%)	472 (89%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.04
95% C.I.		(0.60, 1.78)
p-value		0.896
Inverse Relative Risk [3]		1.04
95% C.I.		(0.62, 1.73)
p-value		0.896
Risk Difference (%) [4]		0.18
95% C.I.		(-2.50, 2.86)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Population: Intent-to-Treat

Table 34.8
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - QualityMetric Approach

Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	76 (14%)	72 (14%)
Non-responder	66 (12%)	70 (13%)
Missing [1]	387 (73%)	386 (73%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.06
95% C.I.		(0.75, 1.50)
p-value		0.733
Inverse Relative Risk [3]		1.05
95% C.I.		(0.78, 1.42)
p-value		0.733
Risk Difference (%) [4]		0.73
95% C.I.		(-3.45, 4.91)
p-value		0.791

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Population: Intent-to-Treat

Table 34.8
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Week 8, Week 12, Week 16, Week 20 and Week 24 - QualityMetric Approach

Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	96 (18%)	85 (16%)
Non-responder	67 (13%)	72 (14%)
Missing [1]	366 (69%)	371 (70%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.16
95% C.I.		(0.84, 1.59)
p-value		0.377
Inverse Relative Risk [3]		1.13
95% C.I.		(0.86, 1.47)
p-value		0.378
Risk Difference (%) [4]		2.05
95% C.I.		(-2.49, 6.59)
p-value		0.415

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of Sotrovimab over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.14
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Work time missed due to health (%)	n	171	204
		Mean	51.83	56.70
		SD	39.040	39.775
		Median	51.02	58.57
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 15	Work time missed due to health (%)	n	94	110
		Mean	46.34	39.00
		SD	41.998	40.561
		Median	43.84	25.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in work time missed due to health (%)	n	77	88
		Mean	0.66	-11.84
		SD	59.486	52.651
		Median	0.00	0.00
		Min.	-100.0	-100.0
		Max.	100.0	100.0

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.14
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	Work time missed due to health (%)	n	87	107
		Mean	13.17	11.68
		SD	28.345	27.383
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in work time missed due to health (%)	n	56	74
		Mean	-31.74	-38.38
		SD	45.907	48.500
		Median	-18.75	-30.80
		Min.	-100.0	-100.0
		Max.	100.0	71.4

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.14
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	62	63
		Mean	49.03	41.11
		SD	31.032	29.518
		Median	50.00	40.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 15	Impairment while working due to health (%)	n	49	59
		Mean	37.14	29.66
		SD	30.890	23.778
		Median	30.00	20.00
		Min.	0.0	0.0
		Max.	100.0	90.0
	Change from baseline in impairment while working due to health (%)	n	21	26
		Mean	-6.19	-4.23
		SD	41.167	35.908
		Median	0.00	0.00
		Min.	-80.0	-90.0
		Max.	90.0	80.0

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.14
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	Impairment while working due to health (%)	n	62	71
		Mean	23.71	24.37
		SD	18.751	23.036
		Median	20.00	10.00
		Min.	0.0	0.0
		Max.	80.0	100.0
	Change from baseline in impairment while working due to health (%)	n	17	23
		Mean	-23.53	-15.65
		SD	37.573	28.256
		Median	-20.00	0.00
		Min.	-80.0	-90.0
		Max.	50.0	20.0

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.14
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	62	62
		Mean	64.23	53.86
		SD	29.983	32.651
		Median	68.88	66.62
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 15	Overall work impairment due to health (%)	n	49	58
		Mean	46.81	40.70
		SD	34.547	31.431
		Median	49.47	31.90
		Min.	0.0	0.0
		Max.	100.0	98.4
	Change from baseline in overall work impairment due to health (%)	n	21	25
		Mean	-7.99	-7.12
		SD	43.272	42.917
		Median	0.00	-0.67
		Min.	-83.5	-90.0
		Max.	90.0	87.3

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.14
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	Overall work impairment due to health (%)	n	62	70
		Mean	28.68	28.27
		SD	23.261	25.734
		Median	20.00	20.00
		Min.	0.0	0.0
		Max.	92.5	100.0
	Change from baseline in overall work impairment due to health (%)	n	17	22
		Mean	-33.31	-19.33
		SD	41.902	32.904
		Median	-33.10	-18.18
		Min.	-86.9	-90.0
		Max.	59.1	44.6

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.14
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	201	189
		Mean	61.09	54.87
		SD	28.979	31.549
		Median	70.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 15	Activity impairment due to health (%)	n	139	155
		Mean	42.30	34.77
		SD	32.040	29.725
		Median	30.00	20.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in activity impairment due to health (%)	n	90	95
		Mean	-18.78	-17.47
		SD	39.287	38.342
		Median	-15.00	-10.00
		Min.	-90.0	-90.0
		Max.	90.0	80.0

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 4.14
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Day 29	Activity impairment due to health (%)	n	178	177
		Mean	28.03	24.63
		SD	25.646	24.818
		Median	20.00	10.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in activity impairment due to health (%)	n	100	95
		Mean	-32.90	-30.11
		SD	34.708	37.487
		Median	-40.00	-20.00
		Min.	-100.0	-90.0
		Max.	60.0	70.0

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.7
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 15 and Day 29

Domain: Work time missed due to health (%)
Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	90	110
n [2]	77	88
LS Mean (SE)	46.77 (4.723)	39.25 (4.408)
95% C.I.	(37.44, 56.09)	(30.55, 47.96)
LS Mean Change from Baseline (SE)	-2.89 (4.723)	-10.40 (4.408)
95% C.I.	(-12.21, 6.44)	(-19.10, -1.69)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-7.51 (6.469)
95% C.I.		(-20.29, 5.26)
p-value		0.247
Corrected Hedge’s g (SE) [3]		-0.18 (0.156)
95% C.I.		(-0.49, 0.13)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.7
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 15 and Day 29

Domain: Work time missed due to health (%)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	90	110
n [2]	56	74
LS Mean (SE)	13.55 (3.937)	13.35 (3.419)
95% C.I.	(5.76, 21.34)	(6.59, 20.12)
LS Mean Change from Baseline (SE)	-36.11 (3.937)	-36.30 (3.419)
95% C.I.	(-43.90, -28.32)	(-43.06, -29.54)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.19 (5.222)
95% C.I.		(-10.53, 10.14)
p-value		0.971
Corrected Hedge’s g (SE) [3]		-0.01 (0.177)
95% C.I.		(-0.35, 0.34)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.7
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 15 and Day 29

Domain: Impairment while working due to health (%)
Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	28	34
n [2]	21	26
LS Mean (SE)	48.83 (6.650)	36.60 (5.977)
95% C.I.	(35.45, 62.20)	(24.58, 48.62)
LS Mean Change from Baseline (SE)	2.05 (6.650)	-10.17 (5.977)
95% C.I.	(-11.33, 15.43)	(-22.20, 1.85)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-12.22 (9.115)
95% C.I.		(-30.56, 6.11)
p-value		0.186
Corrected Hedge’s g (SE) [3]		-0.39 (0.296)
95% C.I.		(-0.97, 0.19)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.7
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 15 and Day 29

Domain: Impairment while working due to health (%)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	28	34
n [2]	17	23
LS Mean (SE)	24.03 (4.632)	25.00 (4.043)
95% C.I.	(14.66, 33.40)	(16.81, 33.18)
LS Mean Change from Baseline (SE)	-22.74 (4.632)	-21.78 (4.043)
95% C.I.	(-32.11, -13.37)	(-29.96, -13.60)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.96 (6.179)
95% C.I.		(-11.54, 13.47)
p-value		0.877
Corrected Hedge’s g (SE) [3]		0.05 (0.320)
95% C.I.		(-0.58, 0.68)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.7
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 15 and Day 29

Domain: Overall work impairment due to health (%)
Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	28	33
n [2]	21	25
LS Mean (SE)	58.87 (7.526)	47.25 (6.871)
95% C.I.	(43.71, 74.04)	(33.40, 61.10)
LS Mean Change from Baseline (SE)	-0.34 (7.526)	-11.97 (6.871)
95% C.I.	(-15.51, 14.83)	(-25.81, 1.88)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-11.62 (10.320)
95% C.I.		(-32.42, 9.18)
p-value		0.266
Corrected Hedge’s g (SE) [3]		-0.33 (0.298)
95% C.I.		(-0.92, 0.25)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.7
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 15 and Day 29

Domain: Overall work impairment due to health (%)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	28	33
n [2]	17	22
LS Mean (SE)	27.74 (5.606)	31.22 (5.027)
95% C.I.	(16.38, 39.10)	(21.03, 41.41)
LS Mean Change from Baseline (SE)	-31.47 (5.606)	-27.99 (5.027)
95% C.I.	(-42.83, -20.11)	(-38.18, -17.80)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.48 (7.582)
95% C.I.		(-11.89, 18.85)
p-value		0.649
Corrected Hedge’s g (SE) [3]		0.15 (0.323)
95% C.I.		(-0.49, 0.78)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.7
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 15 and Day 29

Domain: Activity impairment due to health (%)
Visit: Day 15

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	120	122
n [2]	90	95
LS Mean (SE)	44.40 (3.164)	37.86 (3.098)
95% C.I.	(38.16, 50.64)	(31.75, 43.97)
LS Mean Change from Baseline (SE)	-14.61 (3.164)	-21.15 (3.098)
95% C.I.	(-20.85, -8.37)	(-27.26, -15.04)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-6.54 (4.444)
95% C.I.		(-15.30, 2.22)
p-value		0.143
Corrected Hedge’s g (SE) [3]		-0.22 (0.148)
95% C.I.		(-0.51, 0.07)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.7
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 15 and Day 29

Domain: Activity impairment due to health (%)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
n [1]	120	122
n [2]	100	95
LS Mean (SE)	29.47 (2.441)	27.08 (2.484)
95% C.I.	(24.66, 34.28)	(22.18, 31.97)
LS Mean Change from Baseline (SE)	-29.54 (2.441)	-31.93 (2.484)
95% C.I.	(-34.35, -24.72)	(-36.83, -27.04)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.40 (3.490)
95% C.I.		(-9.28, 4.48)
p-value		0.493
Corrected Hedge’s g (SE) [3]		-0.10 (0.143)
95% C.I.		(-0.38, 0.18)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 4.113
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Work time missed due to health (%)	n	177	212
		Mean	52.78	56.59
		SD	39.421	39.803
		Median	55.56	58.57
		Min.	0.0	0.0
		Max.	100.0	100.0
Week 8	Work time missed due to health (%)	n	115	125
		Mean	7.23	5.50
		SD	22.083	18.877
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in work time missed due to health (%)	n	76	89
		Mean	-45.93	-42.87
		SD	39.698	45.572
		Median	-39.78	-43.24
		Min.	-100.0	-100.0
		Max.	33.3	100.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 4.113
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	Work time missed due to health (%)	n	125	132
		Mean	5.22	5.99
		SD	15.860	19.572
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	85.7	100.0
	Change from baseline in work time missed due to health (%)	n	85	96
		Mean	-45.30	-43.58
		SD	39.386	46.670
		Median	-37.50	-42.78
		Min.	-100.0	-100.0
		Max.	15.9	100.0
Week 16	Work time missed due to health (%)	n	42	39
		Mean	0.34	5.17
		SD	1.604	14.611
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	9.1	61.5
	Change from baseline in work time missed due to health (%)	n	25	22
		Mean	-47.37	-52.07
		SD	41.172	37.242
		Median	-29.82	-48.08
		Min.	-100.0	-100.0
		Max.	0.0	0.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 4.113
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	Work time missed due to health (%)	n	87	90
		Mean	5.30	7.81
		SD	19.062	21.016
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in work time missed due to health (%)	n	58	62
		Mean	-47.94	-48.62
		SD	45.045	42.796
		Median	-53.58	-46.88
		Min.	-100.0	-100.0
		Max.	100.0	54.2
Week 24	Work time missed due to health (%)	n	98	104
		Mean	1.81	5.32
		SD	8.020	17.466
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	50.0	100.0
	Change from baseline in work time missed due to health (%)	n	69	75
		Mean	-48.69	-45.17
		SD	39.134	45.336
		Median	-47.50	-40.00
		Min.	-100.0	-100.0
		Max.	27.8	81.8

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 4.113
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Impairment while working due to health (%)	n	65	69
		Mean	49.85	41.88
		SD	32.186	30.500
		Median	50.00	40.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Week 8	Impairment while working due to health (%)	n	106	118
		Mean	16.04	20.76
		SD	15.411	23.467
		Median	10.00	10.00
		Min.	0.0	0.0
		Max.	90.0	100.0
	Change from baseline in impairment while working due to health (%)	n	30	36
		Mean	-39.33	-19.17
		SD	28.640	31.476
		Median	-50.00	-5.00
		Min.	-80.0	-90.0
		Max.	10.0	50.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 4.113
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	Impairment while working due to health (%)	n	122	127
		Mean	17.79	17.95
		SD	19.562	20.484
		Median	10.00	10.00
		Min.	0.0	0.0
		Max.	90.0	90.0
	Change from baseline in impairment while working due to health (%)	n	31	38
		Mean	-37.42	-23.16
		SD	30.764	36.101
		Median	-40.00	-20.00
		Min.	-90.0	-100.0
		Max.	10.0	60.0
Week 16	Impairment while working due to health (%)	n	42	39
		Mean	10.48	9.49
		SD	20.713	18.057
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	80.0	80.0
	Change from baseline in impairment while working due to health (%)	n	13	12
		Mean	-45.38	-50.00
		SD	39.920	29.542
		Median	-60.00	-50.00
		Min.	-100.0	-100.0
		Max.	20.0	0.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 4.113
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	Impairment while working due to health (%)	n	82	87
		Mean	10.00	12.41
		SD	17.916	22.202
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	90.0	80.0
	Change from baseline in impairment while working due to health (%)	n	20	24
		Mean	-48.50	-33.75
		SD	34.834	40.840
		Median	-50.00	-25.00
		Min.	-100.0	-100.0
		Max.	20.0	60.0
Week 24	Impairment while working due to health (%)	n	96	102
		Mean	8.23	11.08
		SD	16.415	18.288
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	70.0	80.0
	Change from baseline in impairment while working due to health (%)	n	27	28
		Mean	-39.63	-29.64
		SD	34.694	34.263
		Median	-40.00	-30.00
		Min.	-100.0	-100.0
		Max.	20.0	40.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 4.113
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Overall work impairment due to health (%)	n	65	68
		Mean	64.34	54.87
		SD	31.005	33.143
		Median	70.00	69.62
		Min.	0.0	0.0
		Max.	100.0	100.0
Week 8	Overall work impairment due to health (%)	n	106	118
		Mean	18.51	22.24
		SD	19.718	24.949
		Median	10.00	10.00
		Min.	0.0	0.0
		Max.	90.0	100.0
	Change from baseline in overall work impairment due to health (%)	n	30	35
		Mean	-51.29	-32.42
		SD	29.430	31.413
		Median	-55.57	-36.00
		Min.	-86.9	-90.0
		Max.	10.0	16.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 4.113
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	Overall work impairment due to health (%)	n	122	127
		Mean	20.74	20.32
		SD	23.597	22.213
		Median	10.00	10.00
		Min.	0.0	0.0
		Max.	97.1	90.0
	Change from baseline in overall work impairment due to health (%)	n	31	37
		Mean	-51.81	-34.45
		SD	29.079	39.518
		Median	-56.67	-43.33
		Min.	-90.0	-100.0
		Max.	0.0	60.0
Week 16	Overall work impairment due to health (%)	n	42	38
		Mean	10.64	12.74
		SD	20.814	23.515
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	81.8	86.7
	Change from baseline in overall work impairment due to health (%)	n	13	10
		Mean	-52.64	-67.42
		SD	38.948	23.478
		Median	-62.96	-72.16
		Min.	-100.0	-100.0
		Max.	8.5	-20.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 4.113
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	Overall work impairment due to health (%)	n	82	87
		Mean	11.91	15.02
		SD	21.666	25.421
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	92.0	88.0
	Change from baseline in overall work impairment due to health (%)	n	20	23
		Mean	-62.59	-49.18
		SD	32.261	37.653
		Median	-68.88	-54.00
		Min.	-100.0	-100.0
		Max.	6.9	63.3
Week 24	Overall work impairment due to health (%)	n	95	100
		Mean	9.65	13.32
		SD	18.219	21.871
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	85.0	92.0
	Change from baseline in overall work impairment due to health (%)	n	27	25
		Mean	-54.00	-39.18
		SD	32.415	34.076
		Median	-55.26	-43.33
		Min.	-100.0	-100.0
		Max.	8.3	48.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 4.113
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Activity impairment due to health (%)	n	221	207
		Mean	60.23	54.06
		SD	29.503	31.714
		Median	70.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Week 8	Activity impairment due to health (%)	n	236	228
		Mean	21.91	21.84
		SD	22.751	24.497
		Median	10.00	10.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in activity impairment due to health (%)	n	121	112
		Mean	-40.74	-31.43
		SD	32.408	35.814
		Median	-50.00	-40.00
		Min.	-90.0	-90.0
		Max.	70.0	80.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 4.113
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 12	Activity impairment due to health (%)	n	259	250
		Mean	22.97	22.12
		SD	24.016	25.410
		Median	10.00	10.00
		Min.	0.0	0.0
		Max.	90.0	100.0
	Change from baseline in activity impairment due to health (%)	n	127	126
		Mean	-37.80	-26.90
		SD	36.448	35.179
		Median	-40.00	-30.00
		Min.	-90.0	-90.0
		Max.	90.0	70.0
Week 16	Activity impairment due to health (%)	n	71	63
		Mean	14.23	10.32
		SD	27.027	21.096
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	90.0	90.0
	Change from baseline in activity impairment due to health (%)	n	46	45
		Mean	-38.91	-41.33
		SD	39.397	32.932
		Median	-45.00	-50.00
		Min.	-100.0	-90.0
		Max.	90.0	80.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 4.113
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Week 20	Activity impairment due to health (%)	n	156	150
		Mean	12.95	14.93
		SD	21.288	25.270
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	90.0	100.0
	Change from baseline in activity impairment due to health (%)	n	82	82
		Mean	-43.66	-33.29
		SD	37.664	36.449
		Median	-50.00	-35.00
		Min.	-100.0	-100.0
		Max.	50.0	50.0
Week 24	Activity impairment due to health (%)	n	177	173
		Mean	13.28	14.97
		SD	22.900	24.557
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	90.0	90.0
	Change from baseline in activity impairment due to health (%)	n	91	92
		Mean	-44.95	-32.93
		SD	34.396	37.550
		Median	-50.00	-30.00
		Min.	-100.0	-100.0
		Max.	50.0	70.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Work time missed due to health (%)
Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	118	143
n [2]	76	89
LS Mean (SE)	5.07 (2.151)	5.44 (1.986)
95% C.I.	(0.83, 9.32)	(1.51, 9.36)
LS Mean Change from Baseline (SE)	-45.67 (2.151)	-45.31 (1.986)
95% C.I.	(-49.92, -41.42)	(-49.23, -41.39)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.36 (2.928)
95% C.I.		(-5.42, 6.14)
p-value		0.902
Corrected Hedge’s g (SE) [3]		0.02 (0.156)
95% C.I.		(-0.29, 0.33)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Work time missed due to health (%)
Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	118	143
n [2]	85	96
LS Mean (SE)	3.81 (2.147)	8.98 (2.014)
95% C.I.	(-0.42, 8.05)	(5.01, 12.96)
LS Mean Change from Baseline (SE)	-46.93 (2.147)	-41.76 (2.014)
95% C.I.	(-51.17, -42.69)	(-45.74, -37.79)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		5.17 (2.945)
95% C.I.		(-0.65, 10.98)
p-value		0.082
Corrected Hedge’s g (SE) [3]		0.26 (0.150)
95% C.I.		(-0.03, 0.55)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Work time missed due to health (%)
Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	118	143
n [2]	25	22
LS Mean (SE)	1.64 (1.148)	4.66 (1.163)
95% C.I.	(-0.67, 3.95)	(2.32, 7.00)
LS Mean Change from Baseline (SE)	-49.10 (1.148)	-46.08 (1.163)
95% C.I.	(-51.41, -46.79)	(-48.42, -43.75)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		3.02 (1.635)
95% C.I.		(-0.27, 6.30)
p-value		0.072
Corrected Hedge’s g (SE) [3]		0.53 (0.297)
95% C.I.		(-0.05, 1.11)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Work time missed due to health (%)
Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	118	143
n [2]	58	62
LS Mean (SE)	3.96 (2.411)	7.37 (2.346)
95% C.I.	(-0.81, 8.73)	(2.73, 12.01)
LS Mean Change from Baseline (SE)	-46.79 (2.411)	-43.37 (2.346)
95% C.I.	(-51.56, -42.02)	(-48.01, -38.73)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		3.41 (3.361)
95% C.I.		(-3.24, 10.06)
p-value		0.312
Corrected Hedge’s g (SE) [3]		0.18 (0.183)
95% C.I.		(-0.17, 0.54)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Work time missed due to health (%)
Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	118	143
n [2]	69	75
LS Mean (SE)	2.13 (1.708)	4.54 (1.640)
95% C.I.	(-1.25, 5.50)	(1.29, 7.78)
LS Mean Change from Baseline (SE)	-48.62 (1.708)	-46.21 (1.640)
95% C.I.	(-51.99, -45.24)	(-49.45, -42.97)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		2.41 (2.368)
95% C.I.		(-2.27, 7.09)
p-value		0.311
Corrected Hedge’s g (SE) [3]		0.17 (0.167)
95% C.I.		(-0.16, 0.50)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Impairment while working due to health (%)
Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	45	54
n [2]	30	36
LS Mean (SE)	9.13 (3.172)	19.43 (2.876)
95% C.I.	(2.80, 15.46)	(13.69, 25.16)
LS Mean Change from Baseline (SE)	-36.43 (3.172)	-26.13 (2.876)
95% C.I.	(-42.76, -30.10)	(-31.86, -20.39)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		10.30 (4.336)
95% C.I.		(1.65, 18.95)
p-value		0.021
Corrected Hedge’s g (SE) [3]		0.59 (0.252)
95% C.I.		(0.09, 1.08)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Impairment while working due to health (%)
Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	45	54
n [2]	31	38
LS Mean (SE)	13.07 (3.294)	19.84 (2.958)
95% C.I.	(6.51, 19.62)	(13.95, 25.72)
LS Mean Change from Baseline (SE)	-32.49 (3.294)	-25.72 (2.958)
95% C.I.	(-39.05, -25.93)	(-31.61, -19.83)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		6.77 (4.441)
95% C.I.		(-2.07, 15.61)
p-value		0.132
Corrected Hedge’s g (SE) [3]		0.37 (0.244)
95% C.I.		(-0.11, 0.84)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Impairment while working due to health (%)
Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	45	54
n [2]	13	12
LS Mean (SE)	13.30 (7.631)	-1.40 (7.756)
95% C.I.	(-2.60, 29.20)	(-17.58, 14.78)
LS Mean Change from Baseline (SE)	-32.26 (7.631)	-46.95 (7.756)
95% C.I.	(-48.16, -16.36)	(-63.13, -30.78)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-14.70 (10.219)
95% C.I.		(-36.02, 6.62)
p-value		0.166
Corrected Hedge’s g (SE) [3]		-0.52 (0.407)
95% C.I.		(-1.32, 0.28)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Impairment while working due to health (%)
Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	45	54
n [2]	20	24
LS Mean (SE)	11.32 (5.378)	15.08 (4.591)
95% C.I.	(0.54, 22.11)	(5.88, 24.29)
LS Mean Change from Baseline (SE)	-34.23 (5.378)	-30.47 (4.591)
95% C.I.	(-45.01, -23.45)	(-39.67, -21.27)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		3.76 (6.991)
95% C.I.		(-10.25, 17.77)
p-value		0.593
Corrected Hedge’s g (SE) [3]		0.16 (0.303)
95% C.I.		(-0.44, 0.75)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Impairment while working due to health (%)
Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	45	54
n [2]	27	28
LS Mean (SE)	12.48 (3.737)	14.48 (3.626)
95% C.I.	(4.99, 19.96)	(7.22, 21.74)
LS Mean Change from Baseline (SE)	-33.08 (3.737)	-31.08 (3.626)
95% C.I.	(-40.56, -25.59)	(-38.33, -23.82)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		2.00 (5.236)
95% C.I.		(-8.48, 12.48)
p-value		0.704
Corrected Hedge’s g (SE) [3]		0.10 (0.270)
95% C.I.		(-0.43, 0.63)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Overall work impairment due to health (%)
Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	45	53
n [2]	30	35
LS Mean (SE)	14.44 (3.184)	20.16 (2.936)
95% C.I.	(8.09, 20.79)	(14.30, 26.01)
LS Mean Change from Baseline (SE)	-44.50 (3.184)	-38.78 (2.936)
95% C.I.	(-50.85, -38.15)	(-44.63, -32.93)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		5.72 (4.365)
95% C.I.		(-2.99, 14.42)
p-value		0.195
Corrected Hedge’s g (SE) [3]		0.32 (0.250)
95% C.I.		(-0.17, 0.82)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Overall work impairment due to health (%)
Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	45	53
n [2]	31	37
LS Mean (SE)	14.21 (3.704)	23.68 (3.335)
95% C.I.	(6.83, 21.59)	(17.04, 30.32)
LS Mean Change from Baseline (SE)	-44.73 (3.704)	-35.26 (3.335)
95% C.I.	(-52.10, -37.35)	(-41.90, -28.61)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		9.47 (5.001)
95% C.I.		(-0.49, 19.43)
p-value		0.063
Corrected Hedge’s g (SE) [3]		0.46 (0.247)
95% C.I.		(-0.03, 0.94)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Overall work impairment due to health (%)
Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	45	53
n [2]	13	10
LS Mean (SE)	8.89 (6.058)	20.04 (6.279)
95% C.I.	(-3.57, 21.35)	(7.14, 32.95)
LS Mean Change from Baseline (SE)	-50.05 (6.058)	-38.89 (6.279)
95% C.I.	(-62.51, -37.59)	(-51.80, -25.99)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		11.16 (8.680)
95% C.I.		(-6.69, 29.01)
p-value		0.211
Corrected Hedge’s g (SE) [3]		0.51 (0.427)
95% C.I.		(-0.33, 1.35)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Overall work impairment due to health (%)
Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	45	53
n [2]	20	23
LS Mean (SE)	10.68 (5.660)	18.28 (4.901)
95% C.I.	(-0.66, 22.01)	(8.47, 28.09)
LS Mean Change from Baseline (SE)	-48.26 (5.660)	-40.66 (4.901)
95% C.I.	(-59.59, -36.93)	(-50.47, -30.85)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		7.60 (7.201)
95% C.I.		(-6.81, 22.02)
p-value		0.296
Corrected Hedge’s g (SE) [3]		0.31 (0.308)
95% C.I.		(-0.30, 0.91)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Overall work impairment due to health (%)
Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	45	53
n [2]	27	25
LS Mean (SE)	12.13 (4.216)	18.81 (4.294)
95% C.I.	(3.68, 20.58)	(10.21, 27.41)
LS Mean Change from Baseline (SE)	-46.80 (4.216)	-40.13 (4.294)
95% C.I.	(-55.26, -38.35)	(-48.73, -31.53)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		6.67 (6.056)
95% C.I.		(-5.46, 18.81)
p-value		0.276
Corrected Hedge’s g (SE) [3]		0.30 (0.279)
95% C.I.		(-0.24, 0.85)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Activity impairment due to health (%)
Visit: Week 8

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	161	160
n [2]	121	112
LS Mean (SE)	20.34 (2.112)	23.89 (2.166)
95% C.I.	(16.18, 24.50)	(19.62, 28.15)
LS Mean Change from Baseline (SE)	-36.01 (2.112)	-32.47 (2.166)
95% C.I.	(-40.17, -31.86)	(-36.74, -28.20)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		3.55 (3.032)
95% C.I.		(-2.43, 9.52)
p-value		0.244
Corrected Hedge’s g (SE) [3]		0.15 (0.131)
95% C.I.		(-0.10, 0.41)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Activity impairment due to health (%)
Visit: Week 12

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	161	160
n [2]	127	126
LS Mean (SE)	21.26 (2.250)	24.65 (2.271)
95% C.I.	(16.83, 25.69)	(20.18, 29.12)
LS Mean Change from Baseline (SE)	-35.09 (2.250)	-31.70 (2.271)
95% C.I.	(-39.52, -30.66)	(-36.17, -27.23)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		3.39 (3.204)
95% C.I.		(-2.92, 9.70)
p-value		0.292
Corrected Hedge’s g (SE) [3]		0.13 (0.126)
95% C.I.		(-0.11, 0.38)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Activity impairment due to health (%)
Visit: Week 16

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	161	160
n [2]	46	45
LS Mean (SE)	14.89 (3.416)	11.68 (3.477)
95% C.I.	(8.11, 21.66)	(4.78, 18.58)
LS Mean Change from Baseline (SE)	-41.47 (3.416)	-44.67 (3.477)
95% C.I.	(-48.24, -34.69)	(-51.57, -37.77)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-3.20 (4.849)
95% C.I.		(-12.82, 6.41)
p-value		0.511
Corrected Hedge’s g (SE) [3]		-0.14 (0.210)
95% C.I.		(-0.55, 0.27)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Activity impairment due to health (%)
Visit: Week 20

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	161	160
n [2]	82	82
LS Mean (SE)	13.34 (2.422)	19.03 (2.433)
95% C.I.	(8.56, 18.11)	(14.24, 23.83)
LS Mean Change from Baseline (SE)	-43.02 (2.422)	-37.32 (2.433)
95% C.I.	(-47.79, -38.24)	(-42.12, -32.53)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		5.69 (3.436)
95% C.I.		(-1.08, 12.47)
p-value		0.099
Corrected Hedge’s g (SE) [3]		0.26 (0.157)
95% C.I.		(-0.05, 0.57)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 34.3
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Week 8, Week 12, Week 16, Week 20 and Week 24

Domain: Activity impairment due to health (%)
Visit: Week 24

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n [1]	161	160
n [2]	91	92
LS Mean (SE)	11.43 (2.258)	16.99 (2.271)
95% C.I.	(6.98, 15.88)	(12.51, 21.46)
LS Mean Change from Baseline (SE)	-44.92 (2.258)	-39.37 (2.271)
95% C.I.	(-49.38, -40.47)	(-43.85, -34.89)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		5.55 (3.201)
95% C.I.		(-0.76, 11.87)
p-value		0.085
Corrected Hedge’s g (SE) [3]		0.26 (0.148)
95% C.I.		(-0.04, 0.55)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, baseline, visit, baseline by visit and treatment by visit interactions.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 22.14
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	473	472
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	23 (5%)	4 (<1%)
Hospitalized > 24 hours	23 (5%)	4 (<1%)
Death	1 (<1%)	0
Alive and not hospitalized > 24 hours	445 (94%)	462 (98%)
Missing [1]	5 (1%)	6 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.35
95% C.I.		(0.17, 0.73)
p-value		0.005
Relative Risk [3]		0.36
95% C.I.		(0.18, 0.74)
p-value		0.006
Risk Difference (%) [4]		-3.80
95% C.I.		(-6.29, -1.31)
p-value		0.005

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 22.14
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Age Group (<=70, >70)

Age group (years): >70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	56	56
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	7 (13%)	2 (4%)
Hospitalized > 24 hours	6 (11%)	2 (4%)
Death	1 (2%)	0
Alive and not hospitalized > 24 hours	49 (88%)	53 (95%)
Missing [1]	0	1 (2%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.40
95% C.I.		(0.10, 1.64)
p-value		0.205
Relative Risk [3]		0.43
95% C.I.		(0.12, 1.59)
p-value		0.209
Risk Difference (%) [4]		-7.14
95% C.I.		(-17.62, 3.34)
p-value		0.321

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.15
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	473	472
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	31 (7%)	11 (2%)
Hospitalized	23 (5%)	5 (1%)
ER visit	9 (2%)	6 (1%)
Death	1 (<1%)	0
Alive and not hospitalized and no ER visit	437 (92%)	455 (96%)
Missing [1]	5 (1%)	6 (1%)

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.15
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.46
95% C.I.		(0.25, 0.82)
p-value		0.010
Relative Risk [3]		0.48
95% C.I.		(0.27, 0.83)
p-value		0.010
Risk Difference (%) [4]		-4.01
95% C.I.		(-6.93, -1.09)
p-value		0.011

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

Table 22.15
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Age Group (<=70, >70)

Age group (years): >70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	56	56
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	8 (14%)	2 (4%)
Hospitalized	6 (11%)	2 (4%)
ER visit	1 (2%)	0
Death	1 (2%)	0
Alive and not hospitalized and no ER visit	48 (86%)	53 (95%)
Missing [1]	0	1 (2%)

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.15
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Age Group (<=70, >70)

Age group (years): >70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.34
95% C.I.		(0.08, 1.35)
p-value		0.124
Relative Risk [3]		0.37
95% C.I.		(0.10, 1.33)
p-value		0.129
Risk Difference (%) [4]		-8.93
95% C.I.		(-19.83, 1.97)
p-value		0.203

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.21
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	96	98
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	0	1 (1%)
Hospitalized > 24 hours	0	1 (1%)
Death	0	0
Alive and not hospitalized > 24 hours	96 (100%)	97 (99%)
Missing [1]	0	0
VIR-7831 500 mg vs. Placebo:		
Risk Difference (%) [3]		1.02
95% C.I.		(-0.97, 3.01)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.21
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	84	72
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	3 (4%)	1 (1%)
Hospitalized > 24 hours	3 (4%)	1 (1%)
Death	0	0
Alive and not hospitalized > 24 hours	81 (96%)	71 (99%)
Missing [1]	0	0
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.37
95% C.I.		(0.04, 3.61)
p-value		0.389
Risk Difference (%) [3]		-2.18
95% C.I.		(-6.98, 2.62)
p-value		0.625

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.21
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	58	64
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	5 (9%)	1 (2%)
Hospitalized > 24 hours	5 (9%)	1 (2%)
Death	0	0
Alive and not hospitalized > 24 hours	53 (91%)	62 (97%)
Missing [1]	0	1 (2%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.35
95% C.I.		(0.06, 1.90)
p-value		0.224
Risk Difference (%) [3]		-5.50
95% C.I.		(-13.88, 2.89)
p-value		0.256

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.21
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	60	74
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	3 (5%)	0
Hospitalized > 24 hours	3 (5%)	0
Death	0	0
Alive and not hospitalized > 24 hours	56 (93%)	73 (99%)
Missing [1]	1 (2%)	1 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.19
95% C.I.		(0.02, 1.74)
p-value		0.142
Risk Difference (%) [3]		-5.32
95% C.I.		(-12.15, 1.52)
p-value		0.173

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Population: Intent-to-Treat Data as of 27APR2021

Table 22.21
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	183	159
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	16 (9%)	2 (1%)
Hospitalized > 24 hours	15 (8%)	2 (1%)
Death	2 (1%)	0
Alive and not hospitalized > 24 hours	164 (90%)	157 (99%)
Missing [1]	3 (2%)	0
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.11
95% C.I.		(0.03, 0.49)
p-value		0.004
Risk Difference (%) [3]		-9.12
95% C.I.		(-13.87, -4.38)
p-value		<0.001

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.22
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	96	98
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	0	1 (1%)
Hospitalized	0	1 (1%)
ER visit	0	0
Death	0	0
Alive and not hospitalized and no ER visit	96 (100%)	97 (99%)
Missing [1]	0	0
VIR-7831 500 mg vs. Placebo:		
Risk Difference (%) [3]		1.02
95% C.I.		(-0.97, 3.01)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.22
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	84	72
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	3 (4%)	2 (3%)
Hospitalized	3 (4%)	1 (1%)
ER visit	0	1 (1%)
Death	0	0
Alive and not hospitalized and no ER visit	81 (96%)	70 (97%)
Missing [1]	0	0
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.74
95% C.I.		(0.12, 4.59)
p-value		0.750
Risk Difference (%) [3]		-0.79
95% C.I.		(-6.29, 4.70)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.22
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	58	64
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	6 (10%)	1 (2%)
Hospitalized	5 (9%)	1 (2%)
ER visit	1 (2%)	0
Death	0	0
Alive and not hospitalized and no ER visit	52 (90%)	62 (97%)
Missing [1]	0	1 (2%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.29
95% C.I.		(0.06, 1.51)
p-value		0.143
Risk Difference (%) [3]		-7.22
95% C.I.		(-16.14, 1.70)
p-value		0.149

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.22
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	60	74
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	3 (5%)	4 (5%)
Hospitalized	3 (5%)	1 (1%)
ER visit	1 (2%)	3 (4%)
Death	0	0
Alive and not hospitalized and no ER visit	56 (93%)	69 (93%)
Missing [1]	1 (2%)	1 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.99
95% C.I.		(0.25, 3.89)
p-value		0.993
Risk Difference (%) [3]		0.09
95% C.I.		(-8.43, 8.61)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.22
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	183	159
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	24 (13%)	4 (3%)
Hospitalized	15 (8%)	2 (1%)
ER visit	8 (4%)	2 (1%)
Death	2 (1%)	0
Alive and not hospitalized and no ER visit	156 (85%)	155 (97%)
Missing [1]	3 (2%)	0
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.15
95% C.I.		(0.05, 0.44)
p-value		<0.001
Risk Difference (%) [3]		-12.24
95% C.I.		(-17.92, -6.55)
p-value		<0.001

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.28
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Gender

Gender: Male
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	256	229
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	17 (7%)	4 (2%)
Hospitalized > 24 hours	16 (6%)	4 (2%)
Death	2 (<1%)	0
Alive and not hospitalized > 24 hours	237 (93%)	223 (97%)
Missing [1]	2 (<1%)	2 (<1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.34
95% C.I.		(0.13, 0.86)
p-value		0.023
Relative Risk [3]		0.36
95% C.I.		(0.14, 0.87)
p-value		0.025
Risk Difference (%) [4]		-4.80
95% C.I.		(-8.62, -0.98)
p-value		0.023

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.28
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Gender

Gender: Female
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	273	299
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	13 (5%)	2 (<1%)
Hospitalized > 24 hours	13 (5%)	2 (<1%)
Death	0	0
Alive and not hospitalized > 24 hours	257 (94%)	292 (98%)
Missing [1]	3 (1%)	5 (2%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.38
95% C.I.		(0.15, 0.95)
p-value		0.038
Relative Risk [3]		0.40
95% C.I.		(0.17, 0.96)
p-value		0.040
Risk Difference (%) [4]		-3.52
95% C.I.		(-6.79, -0.25)
p-value		0.035

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Table 22.29
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Gender

Gender: Male
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	256	229
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	21 (8%)	5 (2%)
Hospitalized	16 (6%)	4 (2%)
ER visit	5 (2%)	1 (<1%)
Death	2 (<1%)	0
Alive and not hospitalized and no ER visit	233 (91%)	222 (97%)
Missing [1]	2 (<1%)	2 (<1%)

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.29
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Gender

Gender: Male
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.32
95% C.I.		(0.13, 0.76)
p-value		0.010
Relative Risk [3]		0.34
95% C.I.		(0.15, 0.78)
p-value		0.011
Risk Difference (%) [4]		-5.93
95% C.I.		(-10.08, -1.78)
p-value		0.008

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

Table 22.29
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Gender

Gender: Female
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	273	299
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	18 (7%)	8 (3%)
Hospitalized	13 (5%)	3 (1%)
ER visit	5 (2%)	5 (2%)
Death	0	0
Alive and not hospitalized and no ER visit	252 (92%)	286 (96%)
Missing [1]	3 (1%)	5 (2%)

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 22.29
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Gender

Gender: Female
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.55
95% C.I.		(0.27, 1.11)
p-value		0.097
Relative Risk [3]		0.57
95% C.I.		(0.29, 1.11)
p-value		0.100
Risk Difference (%) [4]		-3.34
95% C.I.		(-7.26, 0.57)
p-value		0.112

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 22.35
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Number of Risk Factors

Number of risk factors: <=1
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	307	293
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	15 (5%)	0
Hospitalized > 24 hours	15 (5%)	0
Death	0	0
Alive and not hospitalized > 24 hours	291 (95%)	288 (98%)
Missing [1]	1 (<1%)	5 (2%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.33
95% C.I.		(0.12, 0.90)
p-value		0.031
Relative Risk [3]		0.34
95% C.I.		(0.13, 0.91)
p-value		0.032
Risk Difference (%) [4]		-3.51
95% C.I.		(-6.40, -0.61)
p-value		0.025

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Table 22.35
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Number of Risk Factors

Number of risk factors: 2
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	153	178
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	9 (6%)	1 (<1%)
Hospitalized > 24 hours	8 (5%)	1 (<1%)
Death	1 (<1%)	0
Alive and not hospitalized > 24 hours	141 (92%)	175 (98%)
Missing [1]	3 (2%)	2 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.20
95% C.I.		(0.05, 0.72)
p-value		0.014
Relative Risk [3]		0.21
95% C.I.		(0.06, 0.73)
p-value		0.014
Risk Difference (%) [4]		-6.16
95% C.I.		(-10.82, -1.50)
p-value		0.009

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Table 22.35
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Number of Risk Factors

Number of risk factors: >=3
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	69	57
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	6 (9%)	5 (9%)
Hospitalized > 24 hours	6 (9%)	5 (9%)
Death	1 (1%)	0
Alive and not hospitalized > 24 hours	62 (90%)	52 (91%)
Missing [1]	1 (1%)	0
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.87
95% C.I.		(0.26, 2.96)
p-value		0.829
Relative Risk [3]		0.89
95% C.I.		(0.30, 2.65)
p-value		0.834
Risk Difference (%) [4]		-1.37
95% C.I.		(-11.60, 8.86)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.36
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Number of Risk Factors

Number of risk factors: <=1
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	307	293
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	21 (7%)	5 (2%)
Hospitalized	15 (5%)	1 (<1%)
ER visit	7 (2%)	4 (1%)
Death	0	0
Alive and not hospitalized and no ER visit	285 (93%)	283 (97%)
Missing [1]	1 (<1%)	5 (2%)

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.36
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Number of Risk Factors

Number of risk factors: <=1
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.47
95% C.I.		(0.22, 1.00)
p-value		0.051
Relative Risk [3]		0.49
95% C.I.		(0.23, 1.00)
p-value		0.052
Risk Difference (%) [4]		-3.75
95% C.I.		(-7.31, -0.20)
p-value		0.047

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.36
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Number of Risk Factors

Number of risk factors: 2
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	153	178
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	10 (7%)	3 (2%)
Hospitalized	8 (5%)	1 (<1%)
ER visit	1 (<1%)	2 (1%)
Death	1 (<1%)	0
Alive and not hospitalized and no ER visit	140 (92%)	173 (97%)
Missing [1]	3 (2%)	2 (1%)

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.36
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Number of Risk Factors

Number of risk factors: 2
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.30
95% C.I.		(0.11, 0.88)
p-value		0.028
Relative Risk [3]		0.33
95% C.I.		(0.12, 0.88)
p-value		0.028
Risk Difference (%) [4]		-5.69
95% C.I.		(-10.73, -0.65)
p-value		0.029

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Table 22.36
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Number of Risk Factors

Number of risk factors: >=3
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	69	57
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	8 (12%)	5 (9%)
Hospitalized	6 (9%)	5 (9%)
ER visit	2 (3%)	0
Death	1 (1%)	0
Alive and not hospitalized and no ER visit	60 (87%)	52 (91%)
Missing [1]	1 (1%)	0

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.36
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Number of Risk Factors

Number of risk factors: >=3
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.64
95% C.I.		(0.20, 2.06)
p-value		0.459
Relative Risk [3]		0.68
95% C.I.		(0.24, 1.91)
p-value		0.463
Risk Difference (%) [4]		-4.27
95% C.I.		(-15.09, 6.55)
p-value		0.573

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.42
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	231	234
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	11 (5%)	3 (1%)
Hospitalized > 24 hours	10 (4%)	3 (1%)
Death	2 (<1%)	0
Alive and not hospitalized > 24 hours	218 (94%)	229 (98%)
Missing [1]	2 (<1%)	2 (<1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.37
95% C.I.		(0.13, 1.05)
p-value		0.063
Relative Risk [3]		0.38
95% C.I.		(0.14, 1.05)
p-value		0.064
Risk Difference (%) [4]		-3.49
95% C.I.		(-6.99, 0.01)
p-value		0.058

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 22.42
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	206	212
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	11 (5%)	2 (<1%)
Hospitalized > 24 hours	11 (5%)	2 (<1%)
Death	0	0
Alive and not hospitalized > 24 hours	194 (94%)	210 (>99%)
Missing [1]	1 (<1%)	0
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.15
95% C.I.		(0.03, 0.70)
p-value		0.016
Relative Risk [3]		0.16
95% C.I.		(0.04, 0.72)
p-value		0.017
Risk Difference (%) [4]		-4.88
95% C.I.		(-8.33, -1.43)
p-value		0.006

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.43
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) though Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	231	234
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	12 (5%)	3 (1%)
Hospitalized	10 (4%)	3 (1%)
ER visit	2 (<1%)	0
Death	2 (<1%)	0
Alive and not hospitalized and no ER visit	217 (94%)	229 (98%)
Missing [1]	2 (<1%)	2 (<1%)

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.43
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) though Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.34
95% C.I.		(0.12, 0.95)
p-value		0.040
Relative Risk [3]		0.35
95% C.I.		(0.13, 0.95)
p-value		0.041
Risk Difference (%) [4]		-3.92
95% C.I.		(-7.52, -0.33)
p-value		0.037

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.43
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) though Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	206	212
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	18 (9%)	7 (3%)
Hospitalized	11 (5%)	3 (1%)
ER visit	7 (3%)	4 (2%)
Death	0	0
Alive and not hospitalized and no ER visit	187 (91%)	205 (97%)
Missing [1]	1 (<1%)	0

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.43
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) though Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.34
95% C.I.		(0.14, 0.82)
p-value		0.017
Relative Risk [3]		0.36
95% C.I.		(0.15, 0.84)
p-value		0.018
Risk Difference (%) [4]		-5.92
95% C.I.		(-10.55, -1.30)
p-value		0.015

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.49
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Region

Region: Europe
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	15	14
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	2 (13%)	0
Hospitalized > 24 hours	2 (13%)	0
Death	0	0
Alive and not hospitalized > 24 hours	13 (87%)	13 (93%)
Missing [1]	0	1 (7%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.52
95% C.I.		(0.04, 6.55)
p-value		0.612
Risk Difference (%) [3]		-6.19
95% C.I.		(-28.05, 15.67)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Table 22.49
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Region

Region: North America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	502	503
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	23 (5%)	6 (1%)
Hospitalized > 24 hours	22 (4%)	6 (1%)
Death	2 (<1%)	0
Alive and not hospitalized > 24 hours	474 (94%)	491 (98%)
Missing [1]	5 (<1%)	6 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.41
95% C.I.		(0.21, 0.83)
p-value		0.013
Risk Difference (%) [3]		-3.19
95% C.I.		(-5.60, -0.78)
p-value		0.010

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.49
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Region

Region: South America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	12	11
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	5 (42%)	0
Hospitalized > 24 hours	5 (42%)	0
Death	0	0
Alive and not hospitalized > 24 hours	7 (58%)	11 (100%)
Missing [1]	0	0
VIR-7831 500 mg vs. Placebo:		
Risk Difference (%) [3]		-41.67
95% C.I.		(-69.56, -13.77)
p-value		0.038

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Table 22.50
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Region

Region: Europe
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	15	14
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	2 (13%)	0
Hospitalized	2 (13%)	0
ER visit	0	0
Death	0	0
Alive and not hospitalized and no ER visit	13 (87%)	13 (93%)
Missing [1]	0	1 (7%)

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), region (North America, Europe, South America) and region by treatment interaction using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Table 22.50
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Region

Region: Europe
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.52
95% C.I.		(0.04, 6.58)
p-value		0.617
Relative Risk [3]		0.56
95% C.I.		(0.06, 5.21)
p-value		0.612
Risk Difference (%) [4]		-6.19
95% C.I.		(-28.05, 15.67)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), region (North America, Europe, South America) and region by treatment interaction using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Table 22.50
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Region

Region: North America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	502	503
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	31 (6%)	12 (2%)
Hospitalized	22 (4%)	7 (1%)
ER visit	9 (2%)	5 (<1%)
Death	2 (<1%)	0
Alive and not hospitalized and no ER visit	466 (93%)	485 (96%)
Missing [1]	5 (<1%)	6 (1%)

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), region (North America, Europe, South America) and region by treatment interaction using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Table 22.50
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Region

Region: North America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.48
95% C.I.		(0.27, 0.85)
p-value		0.013
Relative Risk [3]		0.50
95% C.I.		(0.29, 0.86)
p-value		0.014
Risk Difference (%) [4]		-3.59
95% C.I.		(-6.37, -0.81)
p-value		0.012

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), region (North America, Europe, South America) and region by treatment interaction using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Table 22.50
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Region

Region: South America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	12	11
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	6 (50%)	1 (9%)
Hospitalized	5 (42%)	0
ER visit	1 (8%)	1 (9%)
Death	0	0
Alive and not hospitalized and no ER visit	6 (50%)	10 (91%)
Missing [1]	0	0

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), region (North America, Europe, South America) and region by treatment interaction using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.50
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Region

Region: South America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.11
95% C.I.		(0.01, 1.14)
p-value		0.065
Relative Risk [3]		0.20
95% C.I.		(0.03, 1.40)
p-value		0.105
Risk Difference (%) [4]		-40.91
95% C.I.		(-73.91, -7.91)
p-value		0.069

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), region (North America, Europe, South America) and region by treatment interaction using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

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Table 22.16
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	473	472
Progression Status, n (%)		
No Progression [1]	446 (94%)	461 (98%)
Any Progression	21 (4%)	5 (1%)
Category 2: Low flow nasal cannulae/face mask	9 (2%)	5 (1%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	9 (2%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	2 (<1%)	0
Death	1 (<1%)	0
Missing [2]	6 (1%)	6 (1%)

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and age by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

PPD

Table 22.16
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.40
95% C.I.		(0.19, 0.81)
p-value		0.012
Relative Risk [4]		0.41
95% C.I.		(0.21, 0.82)
p-value		0.012
Risk Difference (%) [5]		-3.38
95% C.I.		(-5.87, -0.88)
p-value		0.013

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and age by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point. Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.16
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Age Group (<=70, >70)

Age group (years): >70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	56	56
Progression Status, n (%)		
No Progression [1]	49 (88%)	53 (95%)
Any Progression	7 (13%)	2 (4%)
Category 2: Low flow nasal cannulae/face mask	3 (5%)	2 (4%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	1 (2%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	2 (4%)	0
Death	1 (2%)	0
Missing [2]	0	1 (2%)

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and age by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point. Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.16
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Age Group (<=70, >70)

Age group (years): >70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.40
95% C.I.		(0.10, 1.62)
p-value		0.197
Relative Risk [4]		0.43
95% C.I.		(0.12, 1.57)
p-value		0.201
Risk Difference (%) [5]		-7.14
95% C.I.		(-17.62, 3.34)
p-value		0.321

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and age by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point. Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.23
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	96	98
Progression Status, n (%)		
No Progression [1]	96 (100%)	96 (98%)
Any Progression	0	2 (2%)
Category 2: Low flow nasal cannulae/face mask	0	2 (2%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	0	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	0	0
Death	0	0
Missing [2]	0	0
VIR-7831 500 mg vs. Placebo:		
Risk Difference (%) [4]		2.04
95% C.I.		(-0.76, 4.84)
p-value		0.498

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.

PPD

Table 22.23
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	84	72
Progression Status, n (%)		
No Progression [1]	83 (99%)	71 (99%)
Any Progression	1 (1%)	1 (1%)
Category 2: Low flow nasal cannulae/face mask	0	1 (1%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	1 (1%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	0	0
Death	0	0
Missing [2]	0	0

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.

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Table 22.23
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		1.12
95% C.I.		(0.07, 18.23)
p-value		0.939
Risk Difference (%) [4]		0.20
95% C.I.		(-3.36, 3.76)
p-value		>0.999

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.

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Table 22.23
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	58	64
Progression Status, n (%)		
No Progression [1]	54 (93%)	62 (97%)
Any Progression	3 (5%)	1 (2%)
Category 2: Low flow nasal cannulae/face mask	0	1 (2%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	2 (3%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	1 (2%)	0
Death	0	0
Missing [2]	1 (2%)	1 (2%)

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.

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Table 22.23
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.46
95% C.I.		(0.08, 2.62)
p-value		0.381
Risk Difference (%) [4]		-3.77
95% C.I.		(-11.56, 4.02)
p-value		0.423

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.

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Table 22.23
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	60	74
Progression Status, n (%)		
No Progression [1]	56 (93%)	72 (97%)
Any Progression	3 (5%)	1 (1%)
Category 2: Low flow nasal cannulae/face mask	1 (2%)	1 (1%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	2 (3%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	0	0
Death	0	0
Missing [2]	1 (2%)	1 (1%)

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.

PPD

Table 22.23
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.38
95% C.I.		(0.07, 2.16)
p-value		0.275
Risk Difference (%) [4]		-3.96
95% C.I.		(-11.28, 3.35)
p-value		0.408

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.

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Table 22.23
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	183	159
Progression Status, n (%)		
No Progression [1]	162 (89%)	157 (99%)
Any Progression	18 (10%)	2 (1%)
Category 2: Low flow nasal cannulae/face mask	9 (5%)	2 (1%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	4 (2%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	3 (2%)	0
Death	2 (1%)	0
Missing [2]	3 (2%)	0

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.

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Table 22.23
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.10
95% C.I.		(0.02, 0.44)
p-value		0.003
Risk Difference (%) [4]		-10.22
95% C.I.		(-15.15, -5.29)
p-value		<0.001

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.

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Table 22.30
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Gender

Gender: Male
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	256	229
Progression Status, n (%)		
No Progression [1]	238 (93%)	224 (98%)
Any Progression	16 (6%)	3 (1%)
Category 2: Low flow nasal cannulae/face mask	7 (3%)	3 (1%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	4 (2%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	3 (1%)	0
Death	2 (<1%)	0
Missing [2]	2 (<1%)	2 (<1%)

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and gender by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.30
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Gender

Gender: Male
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.29
95% C.I.		(0.11, 0.81)
p-value		0.018
Relative Risk [4]		0.31
95% C.I.		(0.12, 0.83)
p-value		0.020
Risk Difference (%) [5]		-4.85
95% C.I.		(-8.51, -1.19)
p-value		0.017

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and gender by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point. Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

Table 22.30
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Gender

Gender: Female
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	273	299
Progression Status, n (%)		
No Progression [1]	257 (94%)	290 (97%)
Any Progression	12 (4%)	4 (1%)
Category 2: Low flow nasal cannulae/face mask	5 (2%)	4 (1%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	6 (2%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	1 (<1%)	0
Death	0	0
Missing [2]	4 (1%)	5 (2%)

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and gender by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point. Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.30
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Gender

Gender: Female
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.50
95% C.I.		(0.21, 1.14)
p-value		0.101
Relative Risk [4]		0.51
95% C.I.		(0.23, 1.15)
p-value		0.104
Risk Difference (%) [5]		-2.85
95% C.I.		(-6.24, 0.54)
p-value		0.106

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and gender by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point. Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.37
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Number of Risk Factors

Number of risk factors: <=1
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	307	293
Progression Status, n (%)		
No Progression [1]	291 (95%)	286 (98%)
Any Progression	14 (5%)	2 (<1%)
Category 2: Low flow nasal cannulae/face mask	7 (2%)	2 (<1%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	5 (2%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	2 (<1%)	0
Death	0	0
Missing [2]	2 (<1%)	5 (2%)

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.37
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Number of Risk Factors

Number of risk factors: <=1
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.46
95% C.I.		(0.18, 1.13)
p-value		0.090
Relative Risk [4]		0.47
95% C.I.		(0.20, 1.12)
p-value		0.090
Risk Difference (%) [5]		-2.82
95% C.I.		(-5.86, 0.22)
p-value		0.089

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.37
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Number of Risk Factors

Number of risk factors: 2
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	153	178
Progression Status, n (%)		
No Progression [1]	141 (92%)	173 (97%)
Any Progression	9 (6%)	3 (2%)
Category 2: Low flow nasal cannulae/face mask	4 (3%)	3 (2%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	3 (2%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	1 (<1%)	0
Death	1 (<1%)	0
Missing [2]	3 (2%)	2 (1%)

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.37
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Number of Risk Factors

Number of risk factors: 2
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.33
95% C.I.		(0.11, 0.96)
p-value		0.042
Relative Risk [4]		0.35
95% C.I.		(0.13, 0.96)
p-value		0.043
Risk Difference (%) [5]		-5.03
95% C.I.		(-9.94, -0.13)
p-value		0.047

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.37
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Number of Risk Factors

Number of risk factors: >=3
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	69	57
Progression Status, n (%)		
No Progression [1]	63 (91%)	55 (96%)
Any Progression	5 (7%)	2 (4%)
Category 2: Low flow nasal cannulae/face mask	1 (1%)	2 (4%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	2 (3%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	1 (1%)	0
Death	1 (1%)	0
Missing [2]	1 (1%)	0

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.37
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Number of Risk Factors

Number of risk factors: >=3
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.37
95% C.I.		(0.07, 1.95)
p-value		0.244
Relative Risk [4]		0.40
95% C.I.		(0.09, 1.88)
p-value		0.245
Risk Difference (%) [5]		-5.19
95% C.I.		(-13.37, 3.00)
p-value		0.292

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.44
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	231	234
Progression Status, n (%)		
No Progression [1]	218 (94%)	228 (97%)
Any Progression	11 (5%)	4 (2%)
Category 2: Low flow nasal cannulae/face mask	4 (2%)	4 (2%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	3 (1%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	2 (<1%)	0
Death	2 (<1%)	0
Missing [2]	2 (<1%)	2 (<1%)

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.44
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.44
95% C.I.		(0.16, 1.19)
p-value		0.105
Relative Risk [4]		0.46
95% C.I.		(0.18, 1.17)
p-value		0.102
Risk Difference (%) [5]		-3.06
95% C.I.		(-6.66, 0.53)
p-value		0.107

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point. Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.44
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	206	212
Progression Status, n (%)		
No Progression [1]	194 (94%)	209 (99%)
Any Progression	10 (5%)	3 (1%)
Category 2: Low flow nasal cannulae/face mask	5 (2%)	3 (1%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	4 (2%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	1 (<1%)	0
Death	0	0
Missing [2]	2 (<1%)	0

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.44
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.23
95% C.I.		(0.06, 0.84)
p-value		0.026
Relative Risk [4]		0.24
95% C.I.		(0.07, 0.85)
p-value		0.027
Risk Difference (%) [5]		-4.41
95% C.I.		(-7.98, -0.84)
p-value		0.018

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [3] logistic regression, [4] Poisson model.
[5] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point. Categories 2/3 are severe respiratory COVID-19 and category 4 is critical respiratory COVID-19.

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Table 22.51
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Region

Region: Europe
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	15	14
Progression Status, n (%)		
No Progression [1]	13 (87%)	13 (93%)
Any Progression	2 (13%)	0
Category 2: Low flow nasal cannulae/face mask	1 (7%)	0
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	1 (7%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	0	0
Death	0	0
Missing [2]	0	1 (7%)

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), region (North America, Europe, South America) and treatment by region interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.

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Table 22.51
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Region

Region: Europe
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.52
95% C.I.		(0.04, 6.56)
p-value		0.612
Risk Difference (%) [4]		-6.19
95% C.I.		(-28.05, 15.67)
p-value		>0.999

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), region (North America, Europe, South America) and treatment by region interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.

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Table 22.51
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Region

Region: North America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	502	503
Progression Status, n (%)		
No Progression [1]	475 (95%)	490 (97%)
Any Progression	21 (4%)	7 (1%)
Category 2: Low flow nasal cannulae/face mask	10 (2%)	7 (1%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	7 (1%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	2 (<1%)	0
Death	2 (<1%)	0
Missing [2]	6 (1%)	6 (1%)

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), region (North America, Europe, South America) and treatment by region interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.

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Table 22.51
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Region

Region: North America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [3]		0.46
95% C.I.		(0.24, 0.91)
p-value		0.026
Risk Difference (%) [4]		-2.79
95% C.I.		(-5.21, -0.38)
p-value		0.025

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), region (North America, Europe, South America) and treatment by region interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.

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Table 22.51
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Region

Region: South America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	12	11
Progression Status, n (%)		
No Progression [1]	7 (58%)	11 (100%)
Any Progression	5 (42%)	0
Category 2: Low flow nasal cannulae/face mask	1 (8%)	0
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	2 (17%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	2 (17%)	0
Death	0	0
Missing [2]	0	0
VIR-7831 500 mg vs. Placebo:		
Risk Difference (%) [4]		-41.67
95% C.I.		(-69.56, -13.77)
p-value		0.038

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), region (North America, Europe, South America) and treatment by region interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.

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Table 22.17
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	473	472
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	5 (1%)	4 (<1%)
Hospitalized due to non-respiratory complications	4 (<1%)	4 (<1%)
Death	1 (<1%)	0
Alive and not hospitalized due to non-respiratory complications	459 (97%)	461 (98%)
Missing [1]	9 (2%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.78
95% C.I.		(0.35, 1.74)
p-value		0.548
Relative Risk [3]		0.79
95% C.I.		(0.36, 1.72)
p-value		0.548
Risk Difference (%) [4]		-0.63
95% C.I.		(-2.68, 1.42)
p-value		0.687

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, age (<=70, >70 years old) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 22.17
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Age Group (<=70, >70)

Age group (years): >70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	56	56
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	1 (2%)	0
Hospitalized due to non-respiratory complications	0	0
Death	1 (2%)	0
Alive and not hospitalized due to non-respiratory complications	55 (98%)	55 (98%)
Missing [1]	0	1 (2%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		1.00
95% C.I.		(0.06, 16.39)
p-value		>0.999
Relative Risk [3]		1.00
95% C.I.		(0.06, 15.59)
p-value		>0.999
Risk Difference (%) [4]		0.00
95% C.I.		(-4.91, 4.91)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, age (<=70, >70 years old) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.

PPD

Table 22.24
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	96	98
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	0	0
Hospitalized due to non-respiratory complications	0	0
Death	0	0
Alive and not hospitalized due to non-respiratory complications	96 (100%)	98 (100%)
Missing [1]	0	0

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.

PPD

Table 22.24
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)		VIR-7831 500mg (N=528)	
Number of subjects in subgroup	84		72	
Non-Respiratory Complications Status, n (%)				
Hospitalized due to non-respiratory complications and/or Death	2	(2%)	1	(1%)
Hospitalized due to non-respiratory complications	2	(2%)	1	(1%)
Death	0		0	
Alive and not hospitalized due to non-respiratory complications	82	(98%)	71	(99%)
Missing [1]	0		0	

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.

PPD

Table 22.24
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)		VIR-7831 500mg (N=528)	
Number of subjects in subgroup	58		64	
Non-Respiratory Complications Status, n (%)				
Hospitalized due to non-respiratory complications and/or Death	1	(2%)	0	
Hospitalized due to non-respiratory complications	1	(2%)	0	
Death	0		0	
Alive and not hospitalized due to non-respiratory complications	56	(97%)	62	(97%)
Missing [1]	1	(2%)	2	(3%)

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.

PPD

Table 22.24
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)		VIR-7831 500mg (N=528)	
Number of subjects in subgroup	60		74	
Non-Respiratory Complications Status, n (%)				
Hospitalized due to non-respiratory complications and/or Death	0		1	(1%)
Hospitalized due to non-respiratory complications	0		1	(1%)
Death	0		0	
Alive and not hospitalized due to non-respiratory complications	59	(98%)	72	(97%)
Missing [1]	1	(2%)	1	(1%)

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 22.24
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	183	159
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	3 (2%)	1 (<1%)
Hospitalized due to non-respiratory complications	1 (<1%)	1 (<1%)
Death	2 (1%)	0
Alive and not hospitalized due to non-respiratory complications	176 (96%)	158 (>99%)
Missing [1]	4 (2%)	0

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 22.31
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Gender

Gender: Male
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	256	229
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	5 (2%)	2 (<1%)
Hospitalized due to non-respiratory complications	3 (1%)	2 (<1%)
Death	2 (<1%)	0
Alive and not hospitalized due to non-respiratory complications	248 (97%)	224 (98%)
Missing [1]	3 (1%)	3 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.69
95% C.I.		(0.22, 2.15)
p-value		0.524
Relative Risk [3]		0.70
95% C.I.		(0.23, 2.11)
p-value		0.525
Risk Difference (%) [4]		-0.94
95% C.I.		(-3.79, 1.91)
p-value		0.584

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 22.31
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Gender

Gender: Female
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	273	299
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	1 (<1%)	2 (<1%)
Hospitalized due to non-respiratory complications	1 (<1%)	2 (<1%)
Death	0	0
Alive and not hospitalized due to non-respiratory complications	266 (97%)	292 (98%)
Missing [1]	6 (2%)	5 (2%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.91
95% C.I.		(0.32, 2.63)
p-value		0.864
Relative Risk [3]		0.91
95% C.I.		(0.32, 2.57)
p-value		0.864
Risk Difference (%) [4]		-0.22
95% C.I.		(-2.76, 2.32)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 22.38
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Number of Risk Factors

Number of risk factors: <=1
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	307	293
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	2 (<1%)	1 (<1%)
Hospitalized due to non-respiratory complications	2 (<1%)	1 (<1%)
Death	0	0
Alive and not hospitalized due to non-respiratory complications	301 (98%)	287 (98%)
Missing [1]	4 (1%)	5 (2%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		1.05
95% C.I.		(0.33, 3.29)
p-value		0.935
Relative Risk [3]		1.05
95% C.I.		(0.34, 3.21)
p-value		0.935
Risk Difference (%) [4]		0.09
95% C.I.		(-2.15, 2.34)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 22.38
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Number of Risk Factors

Number of risk factors: 2
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	153	178
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	2 (1%)	0
Hospitalized due to non-respiratory complications	1 (<1%)	0
Death	1 (<1%)	0
Alive and not hospitalized due to non-respiratory complications	148 (97%)	176 (99%)
Missing [1]	3 (2%)	2 (1%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		0.34
95% C.I.		(0.06, 1.76)
p-value		0.197
Relative Risk [3]		0.34
95% C.I.		(0.07, 1.75)
p-value		0.198
Risk Difference (%) [4]		-2.14
95% C.I.		(-5.36, 1.07)
p-value		0.256

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 22.38
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Number of Risk Factors

Number of risk factors: >=3
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	69	57
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	2 (3%)	3 (5%)
Hospitalized due to non-respiratory complications	1 (1%)	3 (5%)
Death	1 (1%)	0
Alive and not hospitalized due to non-respiratory complications	65 (94%)	53 (93%)
Missing [1]	2 (3%)	1 (2%)
VIR-7831 500 mg vs. Placebo:		
Odds Ratio [2]		1.23
95% C.I.		(0.29, 5.14)
p-value		0.781
Relative Risk [3]		1.21
95% C.I.		(0.32, 4.63)
p-value		0.781
Risk Difference (%) [4]		1.22
95% C.I.		(-7.40, 9.84)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 22.45
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	231	234
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	3 (1%)	1 (<1%)
Hospitalized due to non-respiratory complications	1 (<1%)	1 (<1%)
Death	2 (<1%)	0
Alive and not hospitalized due to non-respiratory complications	225 (97%)	231 (99%)
Missing [1]	3 (1%)	2 (<1%)

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 22.45
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)		VIR-7831 500mg (N=528)	
Number of subjects in subgroup	206		212	
Non-Respiratory Complications Status, n (%)				
Hospitalized due to non-respiratory complications and/or Death	2	(<1%)	2	(<1%)
Hospitalized due to non-respiratory complications	2	(<1%)	2	(<1%)
Death	0		0	
Alive and not hospitalized due to non-respiratory complications	201	(98%)	209	(99%)
Missing [1]	3	(1%)	1	(<1%)

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 22.52
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Region

Region: Europe
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	15	14
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	0	0
Hospitalized due to non-respiratory complications	0	0
Death	0	0
Alive and not hospitalized due to non-respiratory complications	15 (100%)	13 (93%)
Missing [1]	0	1 (7%)
VIR-7831 500 mg vs. Placebo:		
Risk Difference (%) [2]		7.14
95% C.I.		(-6.35, 20.63)
p-value		0.483

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.
Note: Logistic regression results not presented as both the full model and simple model results are questionable due to low number of events in some regions. Poisson model results not presented as neither the full model nor simple model converged.
[2] P-value is calculated using a 2-sided Fisher’s Exact test.

PPD

Table 22.52
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Region

Region: North America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	502	503
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	6 (1%)	4 (<1%)
Hospitalized due to non-respiratory complications	4 (<1%)	4 (<1%)
Death	2 (<1%)	0
Alive and not hospitalized due to non-respiratory complications	487 (97%)	492 (98%)
Missing [1]	9 (2%)	7 (1%)
VIR-7831 500 mg vs. Placebo:		
Risk Difference (%) [2]		-0.80
95% C.I.		(-2.76, 1.16)
p-value		0.436

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.
Note: Logistic regression results not presented as both the full model and simple model results are questionable due to low number of events in some regions. Poisson model results not presented as neither the full model nor simple model converged.
[2] P-value is calculated using a 2-sided Fisher’s Exact test.

PPD

Table 22.52
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Region

Region: South America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	12	11
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	0	0
Hospitalized due to non-respiratory complications	0	0
Death	0	0
Alive and not hospitalized due to non-respiratory complications	12 (100%)	11 (100%)
Missing [1]	0	0

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.
Note: Logistic regression results not presented as both the full model and simple model results are questionable due to low number of events in some regions. Poisson model results not presented as neither the full model nor simple model converged.
[2] P-value is calculated using a 2-sided Fisher’s Exact test.

PPD

Table 32.13
Summary of Duration in Hospital through Day 90 by Age Group (<=70, >70)

Age group (years): <=70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	473	472
Alive and never entered hospital [1]	441 (93%)	458 (97%)
Entered hospital [2]	24 (5%)	7 (1%)
1 stay	23 (5%)	6 (1%)
2 stays	1 (<1%)	1 (<1%)
>2 stays	0	0
Incomplete follow-up due to study withdrawal	12 (3%)	8 (2%)
Entered hospital prior to study withdrawal	4 (<1%)	1 (<1%)
Withdrawn and never entered hospital	8 (2%)	7 (1%)
Incomplete follow-up due to death [3]	1 (<1%)	0
Entered hospital prior to death	1 (<1%)	0
Deceased and never entered hospital	0	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.13
Summary of Duration in Hospital through Day 90 by Age Group (<=70, >70)

Age group (years): <=70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	449 (95%)	465 (99%)
>0 - <=24 hours	0	1 (<1%)
>1 - <=8 days	17 (4%)	5 (1%)
9 - <=15 days	2 (<1%)	1 (<1%)
16 - <=22 days	2 (<1%)	0
23 - <=29 days	0	0
30 - <=59 days	2 (<1%)	0
60 - <=90 days	1 (<1%)	0
Duration (days) - All subjects [3]		
Mean	0.7	0.1
SD	5.23	0.72
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	11

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.13
Summary of Duration in Hospital through Day 90 by Age Group (<=70, >70)

Age group (years): <=70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	24	7
Mean	13.3	5.0
SD	19.64	3.42
Median	6.0	4.0
IQR	4.0 - 10.0	3.0 - 8.0
Min.	3	1
Max.	86	11

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

Table 32.13
Summary of Duration in Hospital through Day 90 by Age Group (<=70, >70)

Age group (years): >70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	56	56
Alive and never entered hospital [1]	48 (86%)	51 (91%)
Entered hospital [2]	7 (13%)	4 (7%)
1 stay	7 (13%)	4 (7%)
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	1 (2%)	1 (2%)
Entered hospital prior to study withdrawal	1 (2%)	0
Withdrawn and never entered hospital	0	1 (2%)
Incomplete follow-up due to death [3]	3 (5%)	0
Entered hospital prior to death	2 (4%)	0
Deceased and never entered hospital	1 (2%)	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.13
Summary of Duration in Hospital through Day 90 by Age Group (<=70, >70)

Age group (years): >70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	48 (86%)	52 (93%)
>0 - <=24 hours	0	1 (2%)
>1 - <=8 days	4 (7%)	0
9 - <=15 days	1 (2%)	1 (2%)
16 - <=22 days	0	1 (2%)
23 - <=29 days	0	0
30 - <=59 days	0	1 (2%)
60 - <=90 days	3 (5%)	0
Duration (days) - All subjects [3]		
Mean	4.8	1.5
SD	18.46	7.30
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	51

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.13
Summary of Duration in Hospital through Day 90 by Age Group (<=70, >70)

Age group (years): >70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	8	4
Mean	33.9	20.5
SD	39.42	21.39
Median	7.5	15.0
IQR	5.0 - 79.0	7.5 - 33.5
Min.	2	1
Max.	86	51

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 32.14
Analysis of Duration (days) in Hospital through Day 90 by Age Group (<=70, >70)

Age group (years): <=70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	473	472
n	473	472
LS Mean (SE)	0.7 (0.26)	0.1 (0.26)
95% C.I.	(0.2, 1.2)	(-0.4, 0.6)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.6 (0.37)
95% C.I.		(-1.3, 0.1)
p-value		0.108
Corrected Hedge’s g (SE) [1]		-0.1 (0.07)
95% C.I.		(-0.2, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age group (<=70, >70 years old) and treatment by age interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.14
Analysis of Duration (days) in Hospital through Day 90 by Age Group (<=70, >70)

Age group (years): >70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	56	56
n	56	56
LS Mean (SE)	4.8 (0.77)	1.5 (0.77)
95% C.I.	(3.3, 6.3)	(0.0, 3.0)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-3.4 (1.09)
95% C.I.		(-5.5, -1.2)
p-value		0.002
Corrected Hedge’s g (SE) [1]		-0.6 (0.19)
95% C.I.		(-1.0, -0.2)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age group (<=70, >70 years old) and treatment by age interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.22
Summary of Duration in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	96	98
Alive and never entered hospital [1]	96 (100%)	96 (98%)
Entered hospital [2]	0	2 (2%)
1 stay	0	2 (2%)
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	0	0
Entered hospital prior to study withdrawal	0	0
Withdrawn and never entered hospital	0	0
Incomplete follow-up due to death [3]	0	0
Entered hospital prior to death	0	0
Deceased and never entered hospital	0	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.22
Summary of Duration in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	96 (100%)	96 (98%)
>0 - <=24 hours	0	1 (1%)
>1 - <=8 days	0	0
9 - <=15 days	0	1 (1%)
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0
Duration (days) - All subjects [3]		
Mean	0.0	0.2
SD	0.00	1.42
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	0	14

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.22
Summary of Duration in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	0	2
Mean		7.5
SD		9.19
Median		7.5
IQR		1.0 - 14.0
Min.		1
Max.		14

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.22
Summary of Duration in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	84	72
Alive and never entered hospital [1]	80 (95%)	71 (99%)
Entered hospital [2]	3 (4%)	1 (1%)
1 stay	3 (4%)	0
2 stays	0	1 (1%)
>2 stays	0	0
Incomplete follow-up due to study withdrawal	2 (2%)	0
Entered hospital prior to study withdrawal	1 (1%)	0
Withdrawn and never entered hospital	1 (1%)	0
Incomplete follow-up due to death [3]	0	0
Entered hospital prior to death	0	0
Deceased and never entered hospital	0	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.22
Summary of Duration in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	81 (96%)	71 (99%)
>0 - <=24 hours	0	0
>1 - <=8 days	3 (4%)	1 (1%)
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0
Duration (days) - All subjects [3]		
Mean	0.2	0.1
SD	0.84	0.94
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	6	8

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.22
Summary of Duration in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	3	1
Mean	4.3	8.0
SD	1.53	
Median	4.0	8.0
IQR	3.0 - 6.0	8.0 - 8.0
Min.	3	8
Max.	6	8

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.22
Summary of Duration in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
Alive and never entered hospital [1]	53 (91%)	62 (97%)
Entered hospital [2]	5 (9%)	1 (2%)
1 stay	4 (7%)	1 (2%)
2 stays	1 (2%)	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	1 (2%)	2 (3%)
Entered hospital prior to study withdrawal	1 (2%)	1 (2%)
Withdrawn and never entered hospital	0	1 (2%)
Incomplete follow-up due to death [3]	1 (2%)	0
Entered hospital prior to death	1 (2%)	0
Deceased and never entered hospital	0	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.22
Summary of Duration in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	53 (91%)	63 (98%)
>0 - <=24 hours	0	0
>1 - <=8 days	2 (3%)	1 (2%)
9 - <=15 days	1 (2%)	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	1 (2%)	0
60 - <=90 days	1 (2%)	0
Duration (days) - All subjects [3]		
Mean	2.3	0.1
SD	11.42	0.63
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	81	5

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.22
Summary of Duration in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	5	1
Mean	26.4	5.0
SD	32.61	
Median	11.0	5.0
IQR	4.0 - 32.0	5.0 - 5.0
Min.	4	5
Max.	81	5

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.22
Summary of Duration in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	60	74
Alive and never entered hospital [1]	56 (93%)	71 (96%)
Entered hospital [2]	3 (5%)	1 (1%)
1 stay	3 (5%)	1 (1%)
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	1 (2%)	2 (3%)
Entered hospital prior to study withdrawal	0	0
Withdrawn and never entered hospital	1 (2%)	2 (3%)
Incomplete follow-up due to death [3]	0	0
Entered hospital prior to death	0	0
Deceased and never entered hospital	0	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.22
Summary of Duration in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	57 (95%)	73 (99%)
>0 - <=24 hours	0	1 (1%)
>1 - <=8 days	3 (5%)	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0
Duration (days) - All subjects [3]		
Mean	0.4	0.0
SD	1.55	0.12
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	8	1

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.22
Summary of Duration in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	3	1
Mean	7.0	1.0
SD	1.00	
Median	7.0	1.0
IQR	6.0 - 8.0	1.0 - 1.0
Min.	6	1
Max.	8	1

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.22
Summary of Duration in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	183	159
Alive and never entered hospital [1]	161 (88%)	155 (97%)
Entered hospital [2]	17 (9%)	4 (3%)
1 stay	17 (9%)	4 (3%)
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	5 (3%)	0
Entered hospital prior to study withdrawal	1 (<1%)	0
Withdrawn and never entered hospital	4 (2%)	0
Incomplete follow-up due to death [3]	3 (2%)	0
Entered hospital prior to death	2 (1%)	0
Deceased and never entered hospital	1 (<1%)	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.22
Summary of Duration in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	165 (90%)	155 (97%)
>0 - <=24 hours	0	0
>1 - <=8 days	10 (5%)	2 (1%)
9 - <=15 days	2 (1%)	0
16 - <=22 days	2 (1%)	1 (<1%)
23 - <=29 days	0	0
30 - <=59 days	1 (<1%)	1 (<1%)
60 - <=90 days	3 (2%)	0
Duration (days) - All subjects [3]		
Mean	2.2	0.5
SD	11.54	4.25
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	51

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.22
Summary of Duration in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	18	4
Mean	22.8	18.5
SD	30.52	22.46
Median	7.5	10.0
IQR	4.0 - 20.0	3.5 - 33.5
Min.	2	3
Max.	86	51

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.23
Analysis of Duration (days) in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	96	98
n	96	98
LS Mean (SE)	0.0 (0.62)	0.2 (0.62)
95% C.I.	(-1.2, 1.2)	(-1.1, 1.4)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.2 (0.88)
95% C.I.		(-1.6, 1.9)
p-value		0.862
Corrected Hedge’s g (SE) [1]		0.0 (0.14)
95% C.I.		(-0.3, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category and treatment by baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.23
Analysis of Duration (days) in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	84	72
n	84	72
LS Mean (SE)	0.2 (0.67)	0.1 (0.72)
95% C.I.	(-1.2, 1.5)	(-1.3, 1.5)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.0 (0.98)
95% C.I.		(-2.0, 1.9)
p-value		0.965
Corrected Hedge’s g (SE) [1]		0.0 (0.16)
95% C.I.		(-0.3, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category and treatment by baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.23
Analysis of Duration (days) in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
n	58	64
LS Mean (SE)	2.3 (0.80)	0.1 (0.76)
95% C.I.	(0.7, 3.9)	(-1.4, 1.6)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-2.2 (1.11)
95% C.I.		(-4.4, 0.0)
p-value		0.048
Corrected Hedge’s g (SE) [1]		-0.4 (0.18)
95% C.I.		(-0.7, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category and treatment by baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.23
Analysis of Duration (days) in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	60	74
n	60	74
LS Mean (SE)	0.4 (0.79)	0.0 (0.71)
95% C.I.	(-1.2, 1.9)	(-1.4, 1.4)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.3 (1.06)
95% C.I.		(-2.4, 1.7)
p-value		0.752
Corrected Hedge’s g (SE) [1]		-0.1 (0.17)
95% C.I.		(-0.4, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category and treatment by baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.23
Analysis of Duration (days) in Hospital through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	183	159
n	183	159
LS Mean (SE)	2.2 (0.45)	0.5 (0.48)
95% C.I.	(1.4, 3.1)	(-0.5, 1.4)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.8 (0.66)
95% C.I.		(-3.1, -0.5)
p-value		0.008
Corrected Hedge’s g (SE) [1]		-0.3 (0.11)
95% C.I.		(-0.5, -0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category and treatment by baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.31
Summary of Duration in Hospital through Day 90 by Gender

Gender: Male

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	256	229
Alive and never entered hospital [1]	234 (91%)	221 (97%)
Entered hospital [2]	17 (7%)	6 (3%)
1 stay	16 (6%)	5 (2%)
2 stays	1 (<1%)	1 (<1%)
>2 stays	0	0
Incomplete follow-up due to study withdrawal	5 (2%)	3 (1%)
Entered hospital prior to study withdrawal	1 (<1%)	1 (<1%)
Withdrawn and never entered hospital	4 (2%)	2 (<1%)
Incomplete follow-up due to death [3]	3 (1%)	0
Entered hospital prior to death	2 (<1%)	0
Deceased and never entered hospital	1 (<1%)	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.31
Summary of Duration in Hospital through Day 90 by Gender

Gender: Male

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	238 (93%)	223 (97%)
>0 - <=24 hours	0	0
>1 - <=8 days	10 (4%)	4 (2%)
9 - <=15 days	2 (<1%)	2 (<1%)
16 - <=22 days	1 (<1%)	0
23 - <=29 days	0	0
30 - <=59 days	2 (<1%)	0
60 - <=90 days	3 (1%)	0
Duration (days) - All subjects [3]		
Mean	1.6	0.2
SD	9.92	1.36
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	14

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.31
Summary of Duration in Hospital through Day 90 by Gender

Gender: Male

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	18	6
Mean	23.4	7.5
SD	30.63	4.32
Median	6.5	6.5
IQR	4.0 - 32.0	4.0 - 11.0
Min.	2	3
Max.	86	14

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.31
Summary of Duration in Hospital through Day 90 by Gender

Gender: Female

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	273	299
Alive and never entered hospital [1]	255 (93%)	288 (96%)
Entered hospital [2]	14 (5%)	5 (2%)
1 stay	14 (5%)	5 (2%)
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	8 (3%)	6 (2%)
Entered hospital prior to study withdrawal	4 (1%)	0
Withdrawn and never entered hospital	4 (1%)	6 (2%)
Incomplete follow-up due to death [3]	1 (<1%)	0
Entered hospital prior to death	1 (<1%)	0
Deceased and never entered hospital	0	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

Table 32.31
Summary of Duration in Hospital through Day 90 by Gender

Gender: Female

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	259 (95%)	294 (98%)
>0 - <=24 hours	0	2 (<1%)
>1 - <=8 days	11 (4%)	1 (<1%)
9 - <=15 days	1 (<1%)	0
16 - <=22 days	1 (<1%)	1 (<1%)
23 - <=29 days	0	0
30 - <=59 days	0	1 (<1%)
60 - <=90 days	1 (<1%)	0
Duration (days) - All subjects [3]		
Mean	0.6	0.2
SD	5.18	3.09
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	81	51

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.31
Summary of Duration in Hospital through Day 90 by Gender

Gender: Female

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	14	5
Mean	12.1	14.4
SD	20.26	21.40
Median	6.0	3.0
IQR	4.0 - 8.0	1.0 - 16.0
Min.	3	1
Max.	81	51

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

Population: Intent-to-Treat

Table 32.32
Analysis of Duration (days) in Hospital through Day 90 by Gender

Gender: Male

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	256	229
n	256	229
LS Mean (SE)	1.6 (0.36)	0.2 (0.38)
95% C.I.	(0.9, 2.4)	(-0.6, 1.0)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.4 (0.53)
95% C.I.		(-2.5, -0.4)
p-value		0.007
Corrected Hedge’s g (SE) [1]		-0.2 (0.09)
95% C.I.		(-0.4, -0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female) and treatment by gender interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.32
Analysis of Duration (days) in Hospital through Day 90 by Gender

Gender: Female

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	273	299
n	273	299
LS Mean (SE)	0.6 (0.35)	0.2 (0.34)
95% C.I.	(-0.1, 1.3)	(-0.4, 0.9)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.4 (0.49)
95% C.I.		(-1.3, 0.6)
p-value		0.434
Corrected Hedge’s g (SE) [1]		-0.1 (0.08)
95% C.I.		(-0.2, 0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female) and treatment by gender interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.40
Summary of Duration in Hospital through Day 90 by Number of Risk Factors

Number of risk factors: <=1

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	307	293
Alive and never entered hospital [1]	288 (94%)	286 (98%)
Entered hospital [2]	17 (6%)	2 (<1%)
1 stay	17 (6%)	2 (<1%)
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	5 (2%)	5 (2%)
Entered hospital prior to study withdrawal	3 (<1%)	0
Withdrawn and never entered hospital	2 (<1%)	5 (2%)
Incomplete follow-up due to death [3]	1 (<1%)	0
Entered hospital prior to death	1 (<1%)	0
Deceased and never entered hospital	0	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.40
Summary of Duration in Hospital through Day 90 by Number of Risk Factors

Number of risk factors: <=1

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	290 (94%)	291 (>99%)
>0 - <=24 hours	0	1 (<1%)
>1 - <=8 days	12 (4%)	1 (<1%)
9 - <=15 days	3 (<1%)	0
16 - <=22 days	1 (<1%)	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	1 (<1%)	0
Duration (days) - All subjects [3]		
Mean	0.6	0.0
SD	4.67	0.24
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	77	4

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.40
Summary of Duration in Hospital through Day 90 by Number of Risk Factors

Number of risk factors: <=1

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	17	2
Mean	10.7	2.5
SD	17.40	2.12
Median	6.0	2.5
IQR	4.0 - 9.0	1.0 - 4.0
Min.	3	1
Max.	77	4

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.40
Summary of Duration in Hospital through Day 90 by Number of Risk Factors

Number of risk factors: 2

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	153	178
Alive and never entered hospital [1]	140 (92%)	171 (96%)
Entered hospital [2]	8 (5%)	4 (2%)
1 stay	7 (5%)	4 (2%)
2 stays	1 (<1%)	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	5 (3%)	3 (2%)
Entered hospital prior to study withdrawal	1 (<1%)	0
Withdrawn and never entered hospital	4 (3%)	3 (2%)
Incomplete follow-up due to death [3]	2 (1%)	0
Entered hospital prior to death	1 (<1%)	0
Deceased and never entered hospital	1 (<1%)	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.40
Summary of Duration in Hospital through Day 90 by Number of Risk Factors

Number of risk factors: 2

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	144 (94%)	174 (98%)
>0 - <=24 hours	0	1 (<1%)
>1 - <=8 days	6 (4%)	1 (<1%)
9 - <=15 days	0	1 (<1%)
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	1 (<1%)	1 (<1%)
60 - <=90 days	2 (1%)	0
Duration (days) - All subjects [3]		
Mean	1.5	0.4
SD	9.87	3.96
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	51

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.40
Summary of Duration in Hospital through Day 90 by Number of Risk Factors

Number of risk factors: 2

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	9	4
Mean	25.6	17.3
SD	34.07	23.21
Median	6.0	8.5
IQR	5.0 - 32.0	2.0 - 32.5
Min.	2	1
Max.	86	51

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.40
Summary of Duration in Hospital through Day 90 by Number of Risk Factors

Number of risk factors: >=3

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	69	57
Alive and never entered hospital [1]	61 (88%)	52 (91%)
Entered hospital [2]	6 (9%)	5 (9%)
1 stay	6 (9%)	4 (7%)
2 stays	0	1 (2%)
>2 stays	0	0
Incomplete follow-up due to study withdrawal	3 (4%)	1 (2%)
Entered hospital prior to study withdrawal	1 (1%)	1 (2%)
Withdrawn and never entered hospital	2 (3%)	0
Incomplete follow-up due to death [3]	1 (1%)	0
Entered hospital prior to death	1 (1%)	0
Deceased and never entered hospital	0	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.40
Summary of Duration in Hospital through Day 90 by Number of Risk Factors

Number of risk factors: >=3

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	63 (91%)	52 (91%)
>0 - <=24 hours	0	0
>1 - <=8 days	3 (4%)	3 (5%)
9 - <=15 days	0	1 (2%)
16 - <=22 days	1 (1%)	1 (2%)
23 - <=29 days	0	0
30 - <=59 days	1 (1%)	0
60 - <=90 days	1 (1%)	0
Duration (days) - All subjects [3]		
Mean	2.6	0.8
SD	12.59	2.81
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	16

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.40
Summary of Duration in Hospital through Day 90 by Number of Risk Factors

Number of risk factors: >=3

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	6	5
Mean	29.8	8.6
SD	34.35	5.13
Median	13.5	8.0
IQR	4.0 - 58.0	5.0 - 11.0
Min.	4	3
Max.	86	16

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 32.41
Analysis of Duration (days) in Hospital through Day 90 by Number of Risk Factors

Number of risk factors: <=1

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	307	293
n	307	293
LS Mean (SE)	0.6 (0.33)	0.0 (0.34)
95% C.I.	(-0.1, 1.2)	(-0.6, 0.7)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.6 (0.47)
95% C.I.		(-1.5, 0.4)
p-value		0.226
Corrected Hedge’s g (SE) [1]		-0.1 (0.08)
95% C.I.		(-0.3, 0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.41
Analysis of Duration (days) in Hospital through Day 90 by Number of Risk Factors

Number of risk factors: 2

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	153	178
n	153	178
LS Mean (SE)	1.5 (0.47)	0.4 (0.44)
95% C.I.	(0.6, 2.4)	(-0.5, 1.2)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.1 (0.64)
95% C.I.		(-2.4, 0.1)
p-value		0.083
Corrected Hedge’s g (SE) [1]		-0.2 (0.11)
95% C.I.		(-0.4, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.41
Analysis of Duration (days) in Hospital through Day 90 by Number of Risk Factors

Number of risk factors: >=3

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	69	57
n	69	57
LS Mean (SE)	2.6 (0.70)	0.8 (0.77)
95% C.I.	(1.2, 4.0)	(-0.8, 2.3)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.8 (1.04)
95% C.I.		(-3.9, 0.2)
p-value		0.078
Corrected Hedge’s g (SE) [1]		-0.3 (0.18)
95% C.I.		(-0.7, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.49
Summary of Duration in Hospital through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	237	241
Alive and never entered hospital [1]	222 (94%)	234 (97%)
Entered hospital [2]	10 (4%)	5 (2%)
1 stay	10 (4%)	4 (2%)
2 stays	0	1 (<1%)
>2 stays	0	0
Incomplete follow-up due to study withdrawal	5 (2%)	2 (<1%)
Entered hospital prior to study withdrawal	1 (<1%)	0
Withdrawn and never entered hospital	4 (2%)	2 (<1%)
Incomplete follow-up due to death [3]	2 (<1%)	0
Entered hospital prior to death	1 (<1%)	0
Deceased and never entered hospital	1 (<1%)	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.49
Summary of Duration in Hospital through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	226 (95%)	236 (98%)
>0 - <=24 hours	0	0
>1 - <=8 days	7 (3%)	3 (1%)
9 - <=15 days	0	1 (<1%)
16 - <=22 days	1 (<1%)	1 (<1%)
23 - <=29 days	0	0
30 - <=59 days	1 (<1%)	0
60 - <=90 days	2 (<1%)	0
Duration (days) - All subjects [3]		
Mean	1.2	0.2
SD	8.81	1.49
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	16

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.49
Summary of Duration in Hospital through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	11	5
Mean	26.0	9.0
SD	33.51	5.83
Median	7.0	8.0
IQR	6.0 - 58.0	4.0 - 14.0
Min.	2	3
Max.	86	16

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.49
Summary of Duration in Hospital through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	214	218
Alive and never entered hospital [1]	200 (93%)	213 (98%)
Entered hospital [2]	12 (6%)	5 (2%)
1 stay	12 (6%)	5 (2%)
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	4 (2%)	1 (<1%)
Entered hospital prior to study withdrawal	2 (<1%)	1 (<1%)
Withdrawn and never entered hospital	2 (<1%)	0
Incomplete follow-up due to death [3]	1 (<1%)	0
Entered hospital prior to death	1 (<1%)	0
Deceased and never entered hospital	0	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.49
Summary of Duration in Hospital through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	202 (94%)	213 (98%)
>0 - <=24 hours	0	2 (<1%)
>1 - <=8 days	9 (4%)	2 (<1%)
9 - <=15 days	1 (<1%)	0
16 - <=22 days	1 (<1%)	0
23 - <=29 days	0	0
30 - <=59 days	0	1 (<1%)
60 - <=90 days	1 (<1%)	0
Duration (days) - All subjects [3]		
Mean	0.7	0.3
SD	5.81	3.47
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	81	51

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.49
Summary of Duration in Hospital through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	12	5
Mean	12.9	12.2
SD	21.96	21.75
Median	5.0	3.0
IQR	4.0 - 9.5	1.0 - 5.0
Min.	3	1
Max.	81	51

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 32.50
Analysis of Duration (days) in Hospital through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	237	241
n	237	241
LS Mean (SE)	1.2 (0.37)	0.2 (0.36)
95% C.I.	(0.5, 1.9)	(-0.5, 0.9)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.0 (0.51)
95% C.I.		(-2.0, 0.0)
p-value		0.048
Corrected Hedge’s g (SE) [1]		-0.2 (0.09)
95% C.I.		(-0.4, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.50
Analysis of Duration (days) in Hospital through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	214	218
n	214	218
LS Mean (SE)	0.7 (0.38)	0.3 (0.38)
95% C.I.	(0.0, 1.5)	(-0.5, 1.0)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.4 (0.54)
95% C.I.		(-1.5, 0.6)
p-value		0.412
Corrected Hedge’s g (SE) [1]		-0.1 (0.10)
95% C.I.		(-0.3, 0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.58
Summary of Duration in Hospital through Day 90 by Region

Region: Europe

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	15	14
Alive and never entered hospital [1]	13 (87%)	13 (93%)
Entered hospital [2]	2 (13%)	0
1 stay	2 (13%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	0	1 (7%)
Entered hospital prior to study withdrawal	0	0
Withdrawn and never entered hospital	0	1 (7%)
Incomplete follow-up due to death [3]	0	0
Entered hospital prior to death	0	0
Deceased and never entered hospital	0	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.58
Summary of Duration in Hospital through Day 90 by Region

Region: Europe

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	13 (87%)	14 (100%)
>0 - <=24 hours	0	0
>1 - <=8 days	1 (7%)	0
9 - <=15 days	1 (7%)	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0
Duration (days) - All subjects [3]		
Mean	0.9	0.0
SD	2.58	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	9	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

Table 32.58
Summary of Duration in Hospital through Day 90 by Region

Region: Europe

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	2	0
Mean	7.0	
SD	2.83	
Median	7.0	
IQR	5.0 - 9.0	
Min.	5	
Max.	9	

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

Table 32.58
Summary of Duration in Hospital through Day 90 by Region

Region: North America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	502	503
Alive and never entered hospital [1]	469 (93%)	485 (96%)
Entered hospital [2]	24 (5%)	11 (2%)
1 stay	24 (5%)	10 (2%)
2 stays	0	1 (<1%)
>2 stays	0	0
Incomplete follow-up due to study withdrawal	13 (3%)	8 (2%)
Entered hospital prior to study withdrawal	5 (<1%)	1 (<1%)
Withdrawn and never entered hospital	8 (2%)	7 (1%)
Incomplete follow-up due to death [3]	3 (<1%)	0
Entered hospital prior to death	2 (<1%)	0
Deceased and never entered hospital	1 (<1%)	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.58
Summary of Duration in Hospital through Day 90 by Region

Region: North America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	477 (95%)	492 (98%)
>0 - <=24 hours	0	2 (<1%)
>1 - <=8 days	20 (4%)	5 (<1%)
9 - <=15 days	0	2 (<1%)
16 - <=22 days	2 (<1%)	1 (<1%)
23 - <=29 days	0	0
30 - <=59 days	0	1 (<1%)
60 - <=90 days	3 (<1%)	0
Duration (days) - All subjects [3]		
Mean	0.8	0.2
SD	6.67	2.55
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	51

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.58
Summary of Duration in Hospital through Day 90 by Region

Region: North America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	25	11
Mean	15.6	10.6
SD	26.21	14.33
Median	6.0	5.0
IQR	4.0 - 8.0	3.0 - 14.0
Min.	2	1
Max.	86	51

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.58
Summary of Duration in Hospital through Day 90 by Region

Region: South America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	12	11
Alive and never entered hospital [1]	7 (58%)	11 (100%)
Entered hospital [2]	5 (42%)	0
1 stay	4 (33%)	0
2 stays	1 (8%)	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	0	0
Entered hospital prior to study withdrawal	0	0
Withdrawn and never entered hospital	0	0
Incomplete follow-up due to death [3]	1 (8%)	0
Entered hospital prior to death	1 (8%)	0
Deceased and never entered hospital	0	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.58
Summary of Duration in Hospital through Day 90 by Region

Region: South America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	7 (58%)	11 (100%)
>0 - <=24 hours	0	0
>1 - <=8 days	0	0
9 - <=15 days	2 (17%)	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	2 (17%)	0
60 - <=90 days	1 (8%)	0
Duration (days) - All subjects [3]		
Mean	15.6	0.0
SD	26.29	0.00
Median	0.0	0.0
IQR	0.0 - 21.5	0.0 - 0.0
Min.	0	0
Max.	77	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.58
Summary of Duration in Hospital through Day 90 by Region

Region: South America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	5	0
Mean	37.4	
SD	29.69	
Median	32.0	
IQR	11.0 - 58.0	
Min.	9	
Max.	77	

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

Population: Intent-to-Treat

Table 32.59
Analysis of Duration (days) in Hospital through Day 90 by Region

Region: Europe

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	15	14
n	15	14
LS Mean (SE)	0.9 (1.45)	0.0 (1.50)
95% C.I.	(-1.9, 3.8)	(-2.9, 2.9)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.9 (2.09)
95% C.I.		(-5.0, 3.2)
p-value		0.656
Corrected Hedge’s g (SE) [1]		-0.2 (0.37)
95% C.I.		(-0.9, 0.6)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America) and treatment by region interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 32.59
Analysis of Duration (days) in Hospital through Day 90 by Region

Region: North America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	502	503
n	502	503
LS Mean (SE)	0.8 (0.25)	0.2 (0.25)
95% C.I.	(0.3, 1.3)	(-0.3, 0.7)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.5 (0.35)
95% C.I.		(-1.2, 0.2)
p-value		0.126
Corrected Hedge’s g (SE) [1]		-0.1 (0.06)
95% C.I.		(-0.2, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America) and treatment by region interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.59
Analysis of Duration (days) in Hospital through Day 90 by Region

Region: South America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	12	11
n	12	11
LS Mean (SE)	15.6 (1.62)	0.0 (1.70)
95% C.I.	(12.4, 18.8)	(-3.3, 3.3)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-15.6 (2.35)
95% C.I.		(-20.2, -11.0)
p-value		<0.001
Corrected Hedge’s g (SE) [1]		-2.7 (0.57)
95% C.I.		(-3.8, -1.5)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America) and treatment by region interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.11
Summary of Duration in Intensive Care Unit through Day 90 by Age Group (<=70, >70)

Age group (years): <=70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	473	472
Alive and never entered ICU [1]	455 (96%)	464 (98%)
Entered ICU [2]	6 (1%)	0
1 stay	6 (1%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	12 (3%)	8 (2%)
Entered ICU prior to study withdrawal	0	0
Withdrawn and never entered ICU	12 (3%)	8 (2%)
Incomplete follow-up due to death [3]	1 (<1%)	0
Entered ICU prior to death	1 (<1%)	0
Deceased and never entered ICU	0	0
ICU Stay [3]		
0 days	467 (99%)	472 (100%)
1 - <=8 days	1 (<1%)	0
9 - <=15 days	2 (<1%)	0
16 - <=22 days	0	0
23 - <=29 days	1 (<1%)	0
30 - <=59 days	1 (<1%)	0
60 - <=90 days	1 (<1%)	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.11
Summary of Duration in Intensive Care Unit through Day 90 by Age Group (<=70, >70)

Age group (years): <=70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.3	0.0
SD	3.99	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	73	0
Duration (days) - Subjects with event/death [3]		
n	6	0
Mean	27.3	
SD	24.92	
Median	18.5	
IQR	9.0 - 37.0	
Min.	8	
Max.	73	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.11
Summary of Duration in Intensive Care Unit through Day 90 by Age Group (<=70, >70)

Age group (years): >70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	56	56
Alive and never entered ICU [1]	52 (93%)	55 (98%)
Entered ICU [2]	3 (5%)	0
1 stay	3 (5%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	1 (2%)	1 (2%)
Entered ICU prior to study withdrawal	1 (2%)	0
Withdrawn and never entered ICU	0	1 (2%)
Incomplete follow-up due to death [3]	3 (5%)	0
Entered ICU prior to death	2 (4%)	0
Deceased and never entered ICU	1 (2%)	0
ICU Stay [3]		
0 days	52 (93%)	56 (100%)
1 - <=8 days	1 (2%)	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	3 (5%)	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.11
Summary of Duration in Intensive Care Unit through Day 90 by Age Group (<=70, >70)

Age group (years): >70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	4.5	0.0
SD	18.49	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	0
Duration (days) - Subjects with event/death [3]		
n	4	0
Mean	62.5	
SD	37.85	
Median	79.0	
IQR	41.5 - 83.5	
Min.	6	
Max.	86	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 32.12
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Age Group (<=70, >70)

Age group (years): <=70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	473	472
n	473	472
LS Mean (SE)	0.3 (0.23)	0.0 (0.23)
95% C.I.	(-0.1, 0.8)	(-0.5, 0.5)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.3 (0.33)
95% C.I.		(-1.0, 0.3)
p-value		0.287
Corrected Hedge’s g (SE) [1]		-0.1 (0.07)
95% C.I.		(-0.2, 0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age group (<=70, >70 years old) and treatment by age interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.12
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Age Group (<=70, >70)

Age group (years): >70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	56	56
n	56	56
LS Mean (SE)	4.5 (0.67)	0.0 (0.67)
95% C.I.	(3.2, 5.8)	(-1.3, 1.3)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-4.5 (0.95)
95% C.I.		(-6.3, -2.6)
p-value		<0.001
Corrected Hedge’s g (SE) [1]		-0.9 (0.20)
95% C.I.		(-1.3, -0.5)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age group (<=70, >70 years old) and treatment by age interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.20
Summary of Duration in Intensive Care Unit through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	96	98
Alive and never entered ICU [1]	96 (100%)	98 (100%)
Entered ICU [2]	0	0
1 stay	0	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	0	0
Entered ICU prior to study withdrawal	0	0
Withdrawn and never entered ICU	0	0
Incomplete follow-up due to death [3]	0	0
Entered ICU prior to death	0	0
Deceased and never entered ICU	0	0
ICU Stay [3]		
0 days	96 (100%)	98 (100%)
1 - <=8 days	0	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.20
Summary of Duration in Intensive Care Unit through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.0	0.0
SD	0.00	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	0	0
Duration (days) - Subjects with event/death [3]		
n	0	0
Mean		
SD		
Median		
IQR		
Min.		
Max.		

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.20
Summary of Duration in Intensive Care Unit through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	84	72
Alive and never entered ICU [1]	82 (98%)	72 (100%)
Entered ICU [2]	1 (1%)	0
1 stay	1 (1%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	2 (2%)	0
Entered ICU prior to study withdrawal	1 (1%)	0
Withdrawn and never entered ICU	1 (1%)	0
Incomplete follow-up due to death [3]	0	0
Entered ICU prior to death	0	0
Deceased and never entered ICU	0	0
ICU Stay [3]		
0 days	83 (99%)	72 (100%)
1 - <=8 days	1 (1%)	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.20
Summary of Duration in Intensive Care Unit through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.1	0.0
SD	0.65	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	6	0
Duration (days) - Subjects with event/death [3]		
n	1	0
Mean	6.0	
SD		
Median	6.0	
IQR	6.0 - 6.0	
Min.	6	
Max.	6	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.20
Summary of Duration in Intensive Care Unit through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
Alive and never entered ICU [1]	55 (95%)	62 (97%)
Entered ICU [2]	2 (3%)	0
1 stay	2 (3%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	1 (2%)	2 (3%)
Entered ICU prior to study withdrawal	0	0
Withdrawn and never entered ICU	1 (2%)	2 (3%)
Incomplete follow-up due to death [3]	1 (2%)	0
Entered ICU prior to death	1 (2%)	0
Deceased and never entered ICU	0	0
ICU Stay [3]		
0 days	56 (97%)	64 (100%)
1 - <=8 days	0	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	1 (2%)	0
30 - <=59 days	0	0
60 - <=90 days	1 (2%)	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.20
Summary of Duration in Intensive Care Unit through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	1.8	0.0
SD	11.04	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	81	0
Duration (days) - Subjects with event/death [3]		
n	2	0
Mean	52.5	
SD	40.31	
Median	52.5	
IQR	24.0 - 81.0	
Min.	24	
Max.	81	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.20
Summary of Duration in Intensive Care Unit through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	60	74
Alive and never entered ICU [1]	59 (98%)	72 (97%)
Entered ICU [2]	0	0
1 stay	0	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	1 (2%)	2 (3%)
Entered ICU prior to study withdrawal	0	0
Withdrawn and never entered ICU	1 (2%)	2 (3%)
Incomplete follow-up due to death [3]	0	0
Entered ICU prior to death	0	0
Deceased and never entered ICU	0	0
ICU Stay [3]		
0 days	60 (100%)	74 (100%)
1 - <=8 days	0	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.20
Summary of Duration in Intensive Care Unit through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.0	0.0
SD	0.00	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	0	0
Duration (days) - Subjects with event/death [3]		
n	0	0
Mean		
SD		
Median		
IQR		
Min.		
Max.		

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.20
Summary of Duration in Intensive Care Unit through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	183	159
Alive and never entered ICU [1]	171 (93%)	159 (100%)
Entered ICU [2]	6 (3%)	0
1 stay	6 (3%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	5 (3%)	0
Entered ICU prior to study withdrawal	0	0
Withdrawn and never entered ICU	5 (3%)	0
Incomplete follow-up due to death [3]	3 (2%)	0
Entered ICU prior to death	2 (1%)	0
Deceased and never entered ICU	1 (<1%)	0
ICU Stay [3]		
0 days	176 (96%)	159 (100%)
1 - <=8 days	1 (<1%)	0
9 - <=15 days	2 (1%)	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	1 (<1%)	0
60 - <=90 days	3 (2%)	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.20
Summary of Duration in Intensive Care Unit through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	1.7	0.0
SD	10.44	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	0
Duration (days) - Subjects with event/death [3]		
n	7	0
Mean	43.3	
SD	34.69	
Median	37.0	
IQR	9.0 - 77.0	
Min.	8	
Max.	86	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 32.21
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	96	98
n	96	98
LS Mean (SE)	0.0 (0.55)	0.0 (0.54)
95% C.I.	(-1.1, 1.1)	(-1.1, 1.1)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.0 (0.77)
95% C.I.		(-1.5, 1.5)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		0.0 (0.14)
95% C.I.		(-0.3, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category and treatment by baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.21
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	84	72
n	84	72
LS Mean (SE)	0.1 (0.58)	0.0 (0.63)
95% C.I.	(-1.1, 1.2)	(-1.2, 1.2)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.1 (0.86)
95% C.I.		(-1.8, 1.6)
p-value		0.934
Corrected Hedge’s g (SE) [1]		0.0 (0.16)
95% C.I.		(-0.3, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category and treatment by baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.21
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
n	58	64
LS Mean (SE)	1.8 (0.70)	0.0 (0.67)
95% C.I.	(0.4, 3.2)	(-1.3, 1.3)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.8 (0.97)
95% C.I.		(-3.7, 0.1)
p-value		0.063
Corrected Hedge’s g (SE) [1]		-0.3 (0.18)
95% C.I.		(-0.7, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category and treatment by baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.21
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	60	74
n	60	74
LS Mean (SE)	0.0 (0.69)	0.0 (0.62)
95% C.I.	(-1.4, 1.4)	(-1.2, 1.2)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.0 (0.93)
95% C.I.		(-1.8, 1.8)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		0.0 (0.17)
95% C.I.		(-0.3, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category and treatment by baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.21
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	183	159
n	183	159
LS Mean (SE)	1.7 (0.40)	0.0 (0.42)
95% C.I.	(0.9, 2.4)	(-0.8, 0.8)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.7 (0.58)
95% C.I.		(-2.8, -0.5)
p-value		0.005
Corrected Hedge’s g (SE) [1]		-0.3 (0.11)
95% C.I.		(-0.5, -0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category and treatment by baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 32.29
Summary of Duration in Intensive Care Unit through Day 90 by Gender

Gender: Male

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	256	229
Alive and never entered ICU [1]	244 (95%)	226 (99%)
Entered ICU [2]	6 (2%)	0
1 stay	6 (2%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	5 (2%)	3 (1%)
Entered ICU prior to study withdrawal	0	0
Withdrawn and never entered ICU	5 (2%)	3 (1%)
Incomplete follow-up due to death [3]	3 (1%)	0
Entered ICU prior to death	2 (<1%)	0
Deceased and never entered ICU	1 (<1%)	0
ICU Stay [3]		
0 days	249 (97%)	229 (100%)
1 - <=8 days	0	0
9 - <=15 days	2 (<1%)	0
16 - <=22 days	0	0
23 - <=29 days	1 (<1%)	0
30 - <=59 days	1 (<1%)	0
60 - <=90 days	3 (1%)	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.29
Summary of Duration in Intensive Care Unit through Day 90 by Gender

Gender: Male

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	1.2	0.0
SD	8.96	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	0
Duration (days) - Subjects with event/death [3]		
n	7	0
Mean	45.6	
SD	32.43	
Median	37.0	
IQR	13.0 - 77.0	
Min.	9	
Max.	86	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.29
Summary of Duration in Intensive Care Unit through Day 90 by Gender

Gender: Female

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	273	299
Alive and never entered ICU [1]	263 (96%)	293 (98%)
Entered ICU [2]	3 (1%)	0
1 stay	3 (1%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	8 (3%)	6 (2%)
Entered ICU prior to study withdrawal	1 (<1%)	0
Withdrawn and never entered ICU	7 (3%)	6 (2%)
Incomplete follow-up due to death [3]	1 (<1%)	0
Entered ICU prior to death	1 (<1%)	0
Deceased and never entered ICU	0	0
ICU Stay [3]		
0 days	270 (99%)	299 (100%)
1 - <=8 days	2 (<1%)	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	1 (<1%)	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.29
Summary of Duration in Intensive Care Unit through Day 90 by Gender

Gender: Female

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.3	0.0
SD	4.94	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	81	0
Duration (days) - Subjects with event/death [3]		
n	3	0
Mean	31.7	
SD	42.74	
Median	8.0	
IQR	6.0 - 81.0	
Min.	6	
Max.	81	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 32.30
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Gender

Gender: Male

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	256	229
n	256	229
LS Mean (SE)	1.2 (0.32)	0.0 (0.34)
95% C.I.	(0.6, 1.9)	(-0.7, 0.7)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.2 (0.46)
95% C.I.		(-2.2, -0.3)
p-value		0.008
Corrected Hedge’s g (SE) [1]		-0.2 (0.09)
95% C.I.		(-0.4, -0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female) and treatment by gender interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.30
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Gender

Gender: Female

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	273	299
n	273	299
LS Mean (SE)	0.3 (0.31)	0.0 (0.29)
95% C.I.	(-0.3, 1.0)	(-0.6, 0.6)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.3 (0.42)
95% C.I.		(-1.2, 0.5)
p-value		0.413
Corrected Hedge’s g (SE) [1]		-0.1 (0.08)
95% C.I.		(-0.2, 0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female) and treatment by gender interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.38
Summary of Duration in Intensive Care Unit through Day 90 by Number of Risk Factors

Number of risk factors: <=1

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	307	293
Alive and never entered ICU [1]	299 (97%)	288 (98%)
Entered ICU [2]	3 (<1%)	0
1 stay	3 (<1%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	5 (2%)	5 (2%)
Entered ICU prior to study withdrawal	0	0
Withdrawn and never entered ICU	5 (2%)	5 (2%)
Incomplete follow-up due to death [3]	1 (<1%)	0
Entered ICU prior to death	1 (<1%)	0
Deceased and never entered ICU	0	0
ICU Stay [3]		
0 days	304 (>99%)	293 (100%)
1 - <=8 days	0	0
9 - <=15 days	2 (<1%)	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	1 (<1%)	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.38
Summary of Duration in Intensive Care Unit through Day 90 by Number of Risk Factors

Number of risk factors: <=1

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.3	0.0
SD	4.48	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	77	0
Duration (days) - Subjects with event/death [3]		
n	3	0
Mean	33.0	
SD	38.16	
Median	13.0	
IQR	9.0 - 77.0	
Min.	9	
Max.	77	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.38
Summary of Duration in Intensive Care Unit through Day 90 by Number of Risk Factors

Number of risk factors: 2

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	153	178
Alive and never entered ICU [1]	144 (94%)	175 (98%)
Entered ICU [2]	4 (3%)	0
1 stay	4 (3%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	5 (3%)	3 (2%)
Entered ICU prior to study withdrawal	1 (<1%)	0
Withdrawn and never entered ICU	4 (3%)	3 (2%)
Incomplete follow-up due to death [3]	2 (1%)	0
Entered ICU prior to death	1 (<1%)	0
Deceased and never entered ICU	1 (<1%)	0
ICU Stay [3]		
0 days	148 (97%)	178 (100%)
1 - <=8 days	2 (1%)	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	1 (<1%)	0
30 - <=59 days	0	0
60 - <=90 days	2 (1%)	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.38
Summary of Duration in Intensive Care Unit through Day 90 by Number of Risk Factors

Number of risk factors: 2

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	1.3	0.0
SD	9.72	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	0
Duration (days) - Subjects with event/death [3]		
n	5	0
Mean	41.0	
SD	39.46	
Median	24.0	
IQR	8.0 - 81.0	
Min.	6	
Max.	86	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.38
Summary of Duration in Intensive Care Unit through Day 90 by Number of Risk Factors

Number of risk factors: >=3

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	69	57
Alive and never entered ICU [1]	64 (93%)	56 (98%)
Entered ICU [2]	2 (3%)	0
1 stay	2 (3%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	3 (4%)	1 (2%)
Entered ICU prior to study withdrawal	0	0
Withdrawn and never entered ICU	3 (4%)	1 (2%)
Incomplete follow-up due to death [3]	1 (1%)	0
Entered ICU prior to death	1 (1%)	0
Deceased and never entered ICU	0	0
ICU Stay [3]		
0 days	67 (97%)	57 (100%)
1 - <=8 days	0	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	1 (1%)	0
60 - <=90 days	1 (1%)	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.38
Summary of Duration in Intensive Care Unit through Day 90 by Number of Risk Factors

Number of risk factors: >=3

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	1.6	0.0
SD	9.79	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	73	0
Duration (days) - Subjects with event/death [3]		
n	2	0
Mean	55.0	
SD	25.46	
Median	55.0	
IQR	37.0 - 73.0	
Min.	37	
Max.	73	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 32.39
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Number of Risk Factors

Number of risk factors: <=1

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	307	293
n	307	293
LS Mean (SE)	0.3 (0.29)	0.0 (0.30)
95% C.I.	(-0.2, 0.9)	(-0.6, 0.6)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.3 (0.41)
95% C.I.		(-1.1, 0.5)
p-value		0.437
Corrected Hedge’s g (SE) [1]		-0.1 (0.08)
95% C.I.		(-0.2, 0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.39
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Number of Risk Factors

Number of risk factors: 2

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	153	178
n	153	178
LS Mean (SE)	1.3 (0.41)	0.0 (0.38)
95% C.I.	(0.5, 2.1)	(-0.7, 0.7)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.3 (0.56)
95% C.I.		(-2.4, -0.2)
p-value		0.017
Corrected Hedge’s g (SE) [1]		-0.3 (0.11)
95% C.I.		(-0.5, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.39
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Number of Risk Factors

Number of risk factors: >=3

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	69	57
n	69	57
LS Mean (SE)	1.6 (0.61)	0.0 (0.67)
95% C.I.	(0.4, 2.8)	(-1.3, 1.3)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.6 (0.91)
95% C.I.		(-3.4, 0.2)
p-value		0.080
Corrected Hedge’s g (SE) [1]		-0.3 (0.18)
95% C.I.		(-0.7, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.47
Summary of Duration in Intensive Care Unit through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	237	241
Alive and never entered ICU [1]	228 (96%)	239 (>99%)
Entered ICU [2]	3 (1%)	0
1 stay	3 (1%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	5 (2%)	2 (<1%)
Entered ICU prior to study withdrawal	0	0
Withdrawn and never entered ICU	5 (2%)	2 (<1%)
Incomplete follow-up due to death [3]	2 (<1%)	0
Entered ICU prior to death	1 (<1%)	0
Deceased and never entered ICU	1 (<1%)	0
ICU Stay [3]		
0 days	233 (98%)	241 (100%)
1 - <=8 days	0	0
9 - <=15 days	1 (<1%)	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	1 (<1%)	0
60 - <=90 days	2 (<1%)	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.47
Summary of Duration in Intensive Care Unit through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.9	0.0
SD	7.72	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	0
Duration (days) - Subjects with event/death [3]		
n	4	0
Mean	52.3	
SD	33.38	
Median	55.0	
IQR	25.0 - 79.5	
Min.	13	
Max.	86	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.47
Summary of Duration in Intensive Care Unit through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	214	218
Alive and never entered ICU [1]	208 (97%)	217 (>99%)
Entered ICU [2]	2 (<1%)	0
1 stay	2 (<1%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	4 (2%)	1 (<1%)
Entered ICU prior to study withdrawal	0	0
Withdrawn and never entered ICU	4 (2%)	1 (<1%)
Incomplete follow-up due to death [3]	1 (<1%)	0
Entered ICU prior to death	1 (<1%)	0
Deceased and never entered ICU	0	0
ICU Stay [3]		
0 days	212 (>99%)	218 (100%)
1 - <=8 days	1 (<1%)	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	1 (<1%)	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.47
Summary of Duration in Intensive Care Unit through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.4	0.0
SD	5.56	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	81	0
Duration (days) - Subjects with event/death [3]		
n	2	0
Mean	44.5	
SD	51.62	
Median	44.5	
IQR	8.0 - 81.0	
Min.	8	
Max.	81	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.48
Analysis of Duration (days) in Intensive Care Unit through Day 90
by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	237	241
n	237	241
LS Mean (SE)	0.9 (0.31)	0.0 (0.31)
95% C.I.	(0.3, 1.5)	(-0.6, 0.6)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.9 (0.44)
95% C.I.		(-1.7, 0.0)
p-value		0.044
Corrected Hedge’s g (SE) [1]		-0.2 (0.09)
95% C.I.		(-0.4, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.48
Analysis of Duration (days) in Intensive Care Unit through Day 90
by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	214	218
n	214	218
LS Mean (SE)	0.4 (0.33)	0.0 (0.32)
95% C.I.	(-0.2, 1.1)	(-0.6, 0.6)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.4 (0.46)
95% C.I.		(-1.3, 0.5)
p-value		0.366
Corrected Hedge’s g (SE) [1]		-0.1 (0.10)
95% C.I.		(-0.3, 0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 32.56
Summary of Duration in Intensive Care Unit through Day 90 by Region

Region: Europe

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	15	14
Alive and never entered ICU [1]	14 (93%)	13 (93%)
Entered ICU [2]	1 (7%)	0
1 stay	1 (7%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	0	1 (7%)
Entered ICU prior to study withdrawal	0	0
Withdrawn and never entered ICU	0	1 (7%)
Incomplete follow-up due to death [3]	0	0
Entered ICU prior to death	0	0
Deceased and never entered ICU	0	0
ICU Stay [3]		
0 days	14 (93%)	14 (100%)
1 - <=8 days	0	0
9 - <=15 days	1 (7%)	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.56
Summary of Duration in Intensive Care Unit through Day 90 by Region

Region: Europe

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.6	0.0
SD	2.32	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	9	0
Duration (days) - Subjects with event/death [3]		
n	1	0
Mean	9.0	
SD		
Median	9.0	
IQR	9.0 - 9.0	
Min.	9	
Max.	9	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.56
Summary of Duration in Intensive Care Unit through Day 90 by Region

Region: North America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	502	503
Alive and never entered ICU [1]	484 (96%)	495 (98%)
Entered ICU [2]	5 (<1%)	0
1 stay	5 (<1%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	13 (3%)	8 (2%)
Entered ICU prior to study withdrawal	1 (<1%)	0
Withdrawn and never entered ICU	12 (2%)	8 (2%)
Incomplete follow-up due to death [3]	3 (<1%)	0
Entered ICU prior to death	2 (<1%)	0
Deceased and never entered ICU	1 (<1%)	0
ICU Stay [3]		
0 days	496 (99%)	503 (100%)
1 - <=8 days	2 (<1%)	0
9 - <=15 days	1 (<1%)	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	3 (<1%)	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.56
Summary of Duration in Intensive Care Unit through Day 90 by Region

Region: North America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.5	0.0
SD	6.22	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	0
Duration (days) - Subjects with event/death [3]		
n	6	0
Mean	44.5	
SD	39.18	
Median	43.0	
IQR	8.0 - 81.0	
Min.	6	
Max.	86	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.56
Summary of Duration in Intensive Care Unit through Day 90 by Region

Region: South America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	12	11
Alive and never entered ICU [1]	9 (75%)	11 (100%)
Entered ICU [2]	3 (25%)	0
1 stay	3 (25%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	0	0
Entered ICU prior to study withdrawal	0	0
Withdrawn and never entered ICU	0	0
Incomplete follow-up due to death [3]	1 (8%)	0
Entered ICU prior to death	1 (8%)	0
Deceased and never entered ICU	0	0
ICU Stay [3]		
0 days	9 (75%)	11 (100%)
1 - <=8 days	0	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	1 (8%)	0
30 - <=59 days	1 (8%)	0
60 - <=90 days	1 (8%)	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 32.56
Summary of Duration in Intensive Care Unit through Day 90 by Region

Region: South America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	11.5	0.0
SD	23.91	0.00
Median	0.0	0.0
IQR	0.0 - 12.0	0.0 - 0.0
Min.	0	0
Max.	77	0
Duration (days) - Subjects with event/death [3]		
n	3	0
Mean	46.0	
SD	27.62	
Median	37.0	
IQR	24.0 - 77.0	
Min.	24	
Max.	77	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.57
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Region

Region: Europe

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	15	14
n	15	14
LS Mean (SE)	0.6 (1.28)	0.0 (1.32)
95% C.I.	(-1.9, 3.1)	(-2.6, 2.6)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.6 (1.84)
95% C.I.		(-4.2, 3.0)
p-value		0.745
Corrected Hedge’s g (SE) [1]		-0.1 (0.37)
95% C.I.		(-0.8, 0.6)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America) and treatment by region interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.57
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Region

Region: North America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	502	503
n	502	503
LS Mean (SE)	0.5 (0.22)	0.0 (0.22)
95% C.I.	(0.1, 1.0)	(-0.4, 0.4)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.5 (0.31)
95% C.I.		(-1.1, 0.1)
p-value		0.089
Corrected Hedge’s g (SE) [1]		-0.1 (0.06)
95% C.I.		(-0.2, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America) and treatment by region interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.57
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Region

Region: South America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	12	11
n	12	11
LS Mean (SE)	11.5 (1.43)	0.0 (1.49)
95% C.I.	(8.7, 14.3)	(-2.9, 2.9)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-11.5 (2.07)
95% C.I.		(-15.6, -7.4)
p-value		<0.001
Corrected Hedge’s g (SE) [1]		-2.2 (0.53)
95% C.I.		(-3.3, -1.2)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America) and treatment by region interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 32.9
Summary of Duration on Ventilator through Day 90 by Age Group (<=70, >70)

Age group (years): <=70

	Placebo (N=529)		Sotrovimab (500mg IV) (N=528)	
Number of subjects in subgroup	473		472	
Alive and never on ventilation [1]	458	(97%)	464	(98%)
On ventilation [2]	2	(<1%)	0	
1 period	2	(<1%)	0	
2 periods	0		0	
>2 periods	0		0	
Incomplete follow-up due to study withdrawal	12	(3%)	8	(2%)
On ventilation prior to study withdrawal	0		0	
Withdrawn and never on ventilation	12	(3%)	8	(2%)
Incomplete follow-up due to death [3]	1	(<1%)	0	
On ventilation prior to death	0		0	
Deceased and never on ventilation	1	(<1%)	0	
Ventilator use [3]				
0 days	470	(>99%)	472	(100%)
1 - <=8 days	0		0	
9 - <=15 days	1	(<1%)	0	
16 - <=22 days	0		0	
23 - <=29 days	0		0	
30 - <=59 days	1	(<1%)	0	
60 - <=90 days	1	(<1%)	0	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.9
Summary of Duration on Ventilator through Day 90 by Age Group (<=70, >70)

Age group (years): <=70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.3	0.0
SD	3.96	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	71	0
Duration (days) - Subjects with event/death [3]		
n	3	0
Mean	42.7	
SD	31.34	
Median	48.0	
IQR	9.0 - 71.0	
Min.	9	
Max.	71	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.9
Summary of Duration on Ventilator through Day 90 by Age Group (<=70, >70)

Age group (years): >70

	Placebo (N=529)		Sotrovimab (500mg IV) (N=528)	
Number of subjects in subgroup	56		56	
Alive and never on ventilation [1]	52	(93%)	55	(98%)
On ventilation [2]	2	(4%)	0	
1 period	2	(4%)	0	
2 periods	0		0	
>2 periods	0		0	
Incomplete follow-up due to study withdrawal	1	(2%)	1	(2%)
On ventilation prior to study withdrawal	0		0	
Withdrawn and never on ventilation	1	(2%)	1	(2%)
Incomplete follow-up due to death [3]	3	(5%)	0	
On ventilation prior to death	2	(4%)	0	
Deceased and never on ventilation	1	(2%)	0	
Ventilator use [3]				
0 days	53	(95%)	56	(100%)
1 - <=8 days	0		0	
9 - <=15 days	0		0	
16 - <=22 days	0		0	
23 - <=29 days	0		0	
30 - <=59 days	0		0	
60 - <=90 days	3	(5%)	0	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.9
Summary of Duration on Ventilator through Day 90 by Age Group (<=70, >70)

Age group (years): >70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	4.3	0.0
SD	18.20	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	0
Duration (days) - Subjects with event/death [3]		
n	3	0
Mean	80.0	
SD	5.20	
Median	77.0	
IQR	77.0 - 86.0	
Min.	77	
Max.	86	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 32.10
Analysis of Duration (days) on Ventilator through Day 90 by Age Group (<=70, >70)

Age group (years): <=70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	473	472
n	473	472
LS Mean (SE)	0.3 (0.23)	0.0 (0.23)
95% C.I.	(-0.2, 0.7)	(-0.4, 0.4)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.3 (0.32)
95% C.I.		(-0.9, 0.4)
p-value		0.400
Corrected Hedge’s g (SE) [1]		-0.1 (0.07)
95% C.I.		(-0.2, 0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age group (<=70, >70 years old) and treatment by age interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.10
Analysis of Duration (days) on Ventilator through Day 90 by Age Group (<=70, >70)

Age group (years): >70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	56	56
n	56	56
LS Mean (SE)	4.3 (0.66)	0.0 (0.66)
95% C.I.	(3.0, 5.6)	(-1.3, 1.3)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-4.3 (0.93)
95% C.I.		(-6.1, -2.5)
p-value		<0.001
Corrected Hedge’s g (SE) [1]		-0.9 (0.20)
95% C.I.		(-1.3, -0.5)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age group (<=70, >70 years old) and treatment by age interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Table 32.18
Summary of Duration on Ventilator through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	96	98
Alive and never on ventilation [1]	96 (100%)	98 (100%)
On ventilation [2]	0	0
1 period	0	0
2 periods	0	0
>2 periods	0	0
Incomplete follow-up due to study withdrawal	0	0
On ventilation prior to study withdrawal	0	0
Withdrawn and never on ventilation	0	0
Incomplete follow-up due to death [3]	0	0
On ventilation prior to death	0	0
Deceased and never on ventilation	0	0
Ventilator use [3]		
0 days	96 (100%)	98 (100%)
1 - <=8 days	0	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.18
Summary of Duration on Ventilator through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.0	0.0
SD	0.00	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	0	0
Duration (days) - Subjects with event/death [3]		
n	0	0
Mean		
SD		
Median		
IQR		
Min.		
Max.		

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.18
Summary of Duration on Ventilator through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	84	72
Alive and never on ventilation [1]	82 (98%)	72 (100%)
On ventilation [2]	0	0
1 period	0	0
2 periods	0	0
>2 periods	0	0
Incomplete follow-up due to study withdrawal	2 (2%)	0
On ventilation prior to study withdrawal	0	0
Withdrawn and never on ventilation	2 (2%)	0
Incomplete follow-up due to death [3]	0	0
On ventilation prior to death	0	0
Deceased and never on ventilation	0	0
Ventilator use [3]		
0 days	84 (100%)	72 (100%)
1 - <=8 days	0	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.18
Summary of Duration on Ventilator through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.0	0.0
SD	0.00	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	0	0
Duration (days) - Subjects with event/death [3]		
n	0	0
Mean		
SD		
Median		
IQR		
Min.		
Max.		

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Table 32.18
Summary of Duration on Ventilator through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)		Sotrovimab (500mg IV) (N=528)	
Number of subjects in subgroup	58		64	
Alive and never on ventilation [1]	56	(97%)	62	(97%)
On ventilation [2]	1	(2%)	0	
1 period	1	(2%)	0	
2 periods	0		0	
>2 periods	0		0	
Incomplete follow-up due to study withdrawal	1	(2%)	2	(3%)
On ventilation prior to study withdrawal	0		0	
Withdrawn and never on ventilation	1	(2%)	2	(3%)
Incomplete follow-up due to death [3]	1	(2%)	0	
On ventilation prior to death	1	(2%)	0	
Deceased and never on ventilation	0		0	
Ventilator use [3]				
0 days	57	(98%)	64	(100%)
1 - <=8 days	0		0	
9 - <=15 days	0		0	
16 - <=22 days	0		0	
23 - <=29 days	0		0	
30 - <=59 days	0		0	
60 - <=90 days	1	(2%)	0	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.18
Summary of Duration on Ventilator through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	1.3	0.0
SD	10.11	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	77	0
Duration (days) - Subjects with event/death [3]		
n	1	0
Mean	77.0	
SD		
Median	77.0	
IQR	77.0 - 77.0	
Min.	77	
Max.	77	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Table 32.18
Summary of Duration on Ventilator through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	60	74
Alive and never on ventilation [1]	59 (98%)	72 (97%)
On ventilation [2]	0	0
1 period	0	0
2 periods	0	0
>2 periods	0	0
Incomplete follow-up due to study withdrawal	1 (2%)	2 (3%)
On ventilation prior to study withdrawal	0	0
Withdrawn and never on ventilation	1 (2%)	2 (3%)
Incomplete follow-up due to death [3]	0	0
On ventilation prior to death	0	0
Deceased and never on ventilation	0	0
Ventilator use [3]		
0 days	60 (100%)	74 (100%)
1 - <=8 days	0	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.18
Summary of Duration on Ventilator through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.0	0.0
SD	0.00	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	0	0
Duration (days) - Subjects with event/death [3]		
n	0	0
Mean		
SD		
Median		
IQR		
Min.		
Max.		

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Table 32.18
Summary of Duration on Ventilator through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)		Sotrovimab (500mg IV) (N=528)	
Number of subjects in subgroup	183		159	
Alive and never on ventilation [1]	173	(95%)	159	(100%)
On ventilation [2]	3	(2%)	0	
1 period	3	(2%)	0	
2 periods	0		0	
>2 periods	0		0	
Incomplete follow-up due to study withdrawal	5	(3%)	0	
On ventilation prior to study withdrawal	0		0	
Withdrawn and never on ventilation	5	(3%)	0	
Incomplete follow-up due to death [3]	3	(2%)	0	
On ventilation prior to death	1	(<1%)	0	
Deceased and never on ventilation	2	(1%)	0	
Ventilator use [3]				
0 days	178	(97%)	159	(100%)
1 - <=8 days	0		0	
9 - <=15 days	1	(<1%)	0	
16 - <=22 days	0		0	
23 - <=29 days	0		0	
30 - <=59 days	1	(<1%)	0	
60 - <=90 days	3	(2%)	0	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.18
Summary of Duration on Ventilator through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	1.6	0.0
SD	10.56	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	0
Duration (days) - Subjects with event/death [3]		
n	5	0
Mean	58.2	
SD	30.88	
Median	71.0	
IQR	48.0 - 77.0	
Min.	9	
Max.	86	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Table 32.19
Analysis of Duration (days) on Ventilator through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	96	98
n	96	98
LS Mean (SE)	0.0 (0.54)	0.0 (0.53)
95% C.I.	(-1.1, 1.1)	(-1.0, 1.0)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.0 (0.76)
95% C.I.		(-1.5, 1.5)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		0.0 (0.14)
95% C.I.		(-0.3, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category and treatment by baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.19
Analysis of Duration (days) on Ventilator through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	84	72
n	84	72
LS Mean (SE)	0.0 (0.58)	0.0 (0.62)
95% C.I.	(-1.1, 1.1)	(-1.2, 1.2)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.0 (0.85)
95% C.I.		(-1.7, 1.7)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		0.0 (0.16)
95% C.I.		(-0.3, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category and treatment by baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.19
Analysis of Duration (days) on Ventilator through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
n	58	64
LS Mean (SE)	1.3 (0.69)	0.0 (0.66)
95% C.I.	(0.0, 2.7)	(-1.3, 1.3)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.3 (0.96)
95% C.I.		(-3.2, 0.5)
p-value		0.166
Corrected Hedge’s g (SE) [1]		-0.3 (0.18)
95% C.I.		(-0.6, 0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category and treatment by baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.19
Analysis of Duration (days) on Ventilator through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	60	74
n	60	74
LS Mean (SE)	0.0 (0.68)	0.0 (0.61)
95% C.I.	(-1.3, 1.3)	(-1.2, 1.2)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.0 (0.92)
95% C.I.		(-1.8, 1.8)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		0.0 (0.17)
95% C.I.		(-0.3, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category and treatment by baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.19
Analysis of Duration (days) on Ventilator through Day 90 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	183	159
n	183	159
LS Mean (SE)	1.6 (0.39)	0.0 (0.42)
95% C.I.	(0.8, 2.4)	(-0.8, 0.8)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.6 (0.57)
95% C.I.		(-2.7, -0.5)
p-value		0.006
Corrected Hedge’s g (SE) [1]		-0.3 (0.11)
95% C.I.		(-0.5, -0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category and treatment by baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Table 32.27
Summary of Duration on Ventilator through Day 90 by Gender

Gender: Male

	Placebo (N=529)		Sotrovimab (500mg IV) (N=528)	
Number of subjects in subgroup	256		229	
Alive and never on ventilation [1]	246	(96%)	226	(99%)
On ventilation [2]	3	(1%)	0	
1 period	3	(1%)	0	
2 periods	0		0	
>2 periods	0		0	
Incomplete follow-up due to study withdrawal	5	(2%)	3	(1%)
On ventilation prior to study withdrawal	0		0	
Withdrawn and never on ventilation	5	(2%)	3	(1%)
Incomplete follow-up due to death [3]	3	(1%)	0	
On ventilation prior to death	1	(<1%)	0	
Deceased and never on ventilation	2	(<1%)	0	
Ventilator use [3]				
0 days	251	(98%)	229	(100%)
1 - <=8 days	0		0	
9 - <=15 days	1	(<1%)	0	
16 - <=22 days	0		0	
23 - <=29 days	0		0	
30 - <=59 days	1	(<1%)	0	
60 - <=90 days	3	(1%)	0	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.27
Summary of Duration on Ventilator through Day 90 by Gender

Gender: Male

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	1.1	0.0
SD	8.95	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	0
Duration (days) - Subjects with event/death [3]		
n	5	0
Mean	58.2	
SD	30.88	
Median	71.0	
IQR	48.0 - 77.0	
Min.	9	
Max.	86	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Table 32.27
Summary of Duration on Ventilator through Day 90 by Gender

Gender: Female

	Placebo (N=529)		Sotrovimab (500mg IV) (N=528)	
Number of subjects in subgroup	273		299	
Alive and never on ventilation [1]	264	(97%)	293	(98%)
On ventilation [2]	1	(<1%)	0	
1 period	1	(<1%)	0	
2 periods	0		0	
>2 periods	0		0	
Incomplete follow-up due to study withdrawal	8	(3%)	6	(2%)
On ventilation prior to study withdrawal	0		0	
Withdrawn and never on ventilation	8	(3%)	6	(2%)
Incomplete follow-up due to death [3]	1	(<1%)	0	
On ventilation prior to death	1	(<1%)	0	
Deceased and never on ventilation	0		0	
Ventilator use [3]				
0 days	272	(>99%)	299	(100%)
1 - <=8 days	0		0	
9 - <=15 days	0		0	
16 - <=22 days	0		0	
23 - <=29 days	0		0	
30 - <=59 days	0		0	
60 - <=90 days	1	(<1%)	0	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Table 32.27
Summary of Duration on Ventilator through Day 90 by Gender

Gender: Female

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.3	0.0
SD	4.66	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	77	0
Duration (days) - Subjects with event/death [3]		
n	1	0
Mean	77.0	
SD		
Median	77.0	
IQR	77.0 - 77.0	
Min.	77	
Max.	77	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 32.28
Analysis of Duration (days) on Ventilator through Day 90 by Gender

Gender: Male

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	256	229
n	256	229
LS Mean (SE)	1.1 (0.31)	0.0 (0.33)
95% C.I.	(0.5, 1.7)	(-0.6, 0.6)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.1 (0.45)
95% C.I.		(-2.0, -0.2)
p-value		0.013
Corrected Hedge’s g (SE) [1]		-0.2 (0.09)
95% C.I.		(-0.4, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female) and treatment by gender interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.28
Analysis of Duration (days) on Ventilator through Day 90 by Gender

Gender: Female

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	273	299
n	273	299
LS Mean (SE)	0.3 (0.30)	0.0 (0.29)
95% C.I.	(-0.3, 0.9)	(-0.6, 0.6)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.3 (0.42)
95% C.I.		(-1.1, 0.5)
p-value		0.501
Corrected Hedge’s g (SE) [1]		-0.1 (0.08)
95% C.I.		(-0.2, 0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female) and treatment by gender interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

Table 32.36
Summary of Duration on Ventilator through Day 90 by Number of Risk Factors

Number of risk factors: <=1

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	307	293
Alive and never on ventilation [1]	300 (98%)	288 (98%)
On ventilation [2]	2 (<1%)	0
1 period	2 (<1%)	0
2 periods	0	0
>2 periods	0	0
Incomplete follow-up due to study withdrawal	5 (2%)	5 (2%)
On ventilation prior to study withdrawal	0	0
Withdrawn and never on ventilation	5 (2%)	5 (2%)
Incomplete follow-up due to death [3]	1 (<1%)	0
On ventilation prior to death	1 (<1%)	0
Deceased and never on ventilation	0	0
Ventilator use [3]		
0 days	305 (>99%)	293 (100%)
1 - <=8 days	0	0
9 - <=15 days	1 (<1%)	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	1 (<1%)	0

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.36
Summary of Duration on Ventilator through Day 90 by Number of Risk Factors

Number of risk factors: <=1

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.3	0.0
SD	4.42	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	77	0
Duration (days) - Subjects with event/death [3]		
n	2	0
Mean	43.0	
SD	48.08	
Median	43.0	
IQR	9.0 - 77.0	
Min.	9	
Max.	77	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Table 32.36
Summary of Duration on Ventilator through Day 90 by Number of Risk Factors

Number of risk factors: 2

	Placebo (N=529)		Sotrovimab (500mg IV) (N=528)	
Number of subjects in subgroup	153		178	
Alive and never on ventilation [1]	146	(95%)	175	(98%)
On ventilation [2]	1	(<1%)	0	
1 period	1	(<1%)	0	
2 periods	0		0	
>2 periods	0		0	
Incomplete follow-up due to study withdrawal	5	(3%)	3	(2%)
On ventilation prior to study withdrawal	0		0	
Withdrawn and never on ventilation	5	(3%)	3	(2%)
Incomplete follow-up due to death [3]	2	(1%)	0	
On ventilation prior to death	1	(<1%)	0	
Deceased and never on ventilation	1	(<1%)	0	
Ventilator use [3]				
0 days	151	(99%)	178	(100%)
1 - <=8 days	0		0	
9 - <=15 days	0		0	
16 - <=22 days	0		0	
23 - <=29 days	0		0	
30 - <=59 days	0		0	
60 - <=90 days	2	(1%)	0	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.36
Summary of Duration on Ventilator through Day 90 by Number of Risk Factors

Number of risk factors: 2

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	1.1	0.0
SD	9.30	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	0
Duration (days) - Subjects with event/death [3]		
n	2	0
Mean	81.5	
SD	6.36	
Median	81.5	
IQR	77.0 - 86.0	
Min.	77	
Max.	86	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.36
Summary of Duration on Ventilator through Day 90 by Number of Risk Factors

Number of risk factors: >=3

	Placebo (N=529)		Sotrovimab (500mg IV) (N=528)	
Number of subjects in subgroup	69		57	
Alive and never on ventilation [1]	64	(93%)	56	(98%)
On ventilation [2]	1	(1%)	0	
1 period	1	(1%)	0	
2 periods	0		0	
>2 periods	0		0	
Incomplete follow-up due to study withdrawal	3	(4%)	1	(2%)
On ventilation prior to study withdrawal	0		0	
Withdrawn and never on ventilation	3	(4%)	1	(2%)
Incomplete follow-up due to death [3]	1	(1%)	0	
On ventilation prior to death	0		0	
Deceased and never on ventilation	1	(1%)	0	
Ventilator use [3]				
0 days	67	(97%)	57	(100%)
1 - <=8 days	0		0	
9 - <=15 days	0		0	
16 - <=22 days	0		0	
23 - <=29 days	0		0	
30 - <=59 days	1	(1%)	0	
60 - <=90 days	1	(1%)	0	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.36
Summary of Duration on Ventilator through Day 90 by Number of Risk Factors

Number of risk factors: >=3

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	1.7	0.0
SD	10.25	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	71	0
Duration (days) - Subjects with event/death [3]		
n	2	0
Mean	59.5	
SD	16.26	
Median	59.5	
IQR	48.0 - 71.0	
Min.	48	
Max.	71	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.37
Analysis of Duration (days) on Ventilator through Day 90 by Number of Risk Factors

Number of risk factors: <=1

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	307	293
n	307	293
LS Mean (SE)	0.3 (0.29)	0.0 (0.29)
95% C.I.	(-0.3, 0.8)	(-0.6, 0.6)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.3 (0.41)
95% C.I.		(-1.1, 0.5)
p-value		0.493
Corrected Hedge’s g (SE) [1]		-0.1 (0.08)
95% C.I.		(-0.2, 0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.37
Analysis of Duration (days) on Ventilator through Day 90 by Number of Risk Factors

Number of risk factors: 2

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	153	178
n	153	178
LS Mean (SE)	1.1 (0.40)	0.0 (0.37)
95% C.I.	(0.3, 1.9)	(-0.7, 0.7)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.1 (0.55)
95% C.I.		(-2.1, 0.0)
p-value		0.054
Corrected Hedge’s g (SE) [1]		-0.2 (0.11)
95% C.I.		(-0.4, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.37
Analysis of Duration (days) on Ventilator through Day 90 by Number of Risk Factors

Number of risk factors: >=3

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	69	57
n	69	57
LS Mean (SE)	1.7 (0.60)	0.0 (0.66)
95% C.I.	(0.5, 2.9)	(-1.3, 1.3)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.7 (0.89)
95% C.I.		(-3.5, 0.0)
p-value		0.055
Corrected Hedge’s g (SE) [1]		-0.3 (0.18)
95% C.I.		(-0.7, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

Table 32.45
Summary of Duration on Ventilator through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	237	241
Alive and never on ventilation [1]	228 (96%)	239 (>99%)
On ventilation [2]	2 (<1%)	0
1 period	2 (<1%)	0
2 periods	0	0
>2 periods	0	0
Incomplete follow-up due to study withdrawal	5 (2%)	2 (<1%)
On ventilation prior to study withdrawal	0	0
Withdrawn and never on ventilation	5 (2%)	2 (<1%)
Incomplete follow-up due to death [3]	2 (<1%)	0
On ventilation prior to death	0	0
Deceased and never on ventilation	2 (<1%)	0
Ventilator use [3]		
0 days	233 (98%)	241 (100%)
1 - <=8 days	0	0
9 - <=15 days	1 (<1%)	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	1 (<1%)	0
60 - <=90 days	2 (<1%)	0

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.45
Summary of Duration on Ventilator through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.9	0.0
SD	7.87	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	0
Duration (days) - Subjects with event/death [3]		
n	4	0
Mean	53.5	
SD	33.53	
Median	59.5	
IQR	28.5 - 78.5	
Min.	9	
Max.	86	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Table 32.45
Summary of Duration on Ventilator through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	214	218
Alive and never on ventilation [1]	209 (98%)	217 (>99%)
On ventilation [2]	1 (<1%)	0
1 period	1 (<1%)	0
2 periods	0	0
>2 periods	0	0
Incomplete follow-up due to study withdrawal	4 (2%)	1 (<1%)
On ventilation prior to study withdrawal	0	0
Withdrawn and never on ventilation	4 (2%)	1 (<1%)
Incomplete follow-up due to death [3]	1 (<1%)	0
On ventilation prior to death	1 (<1%)	0
Deceased and never on ventilation	0	0
Ventilator use [3]		
0 days	213 (>99%)	218 (100%)
1 - <=8 days	0	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	1 (<1%)	0

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.45
Summary of Duration on Ventilator through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.4	0.0
SD	5.26	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	77	0
Duration (days) - Subjects with event/death [3]		
n	1	0
Mean	77.0	
SD		
Median	77.0	
IQR	77.0 - 77.0	
Min.	77	
Max.	77	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 32.46
Analysis of Duration (days) on Ventilator through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	237	241
n	237	241
LS Mean (SE)	0.9 (0.31)	0.0 (0.31)
95% C.I.	(0.3, 1.5)	(-0.6, 0.6)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.9 (0.44)
95% C.I.		(-1.8, 0.0)
p-value		0.039
Corrected Hedge’s g (SE) [1]		-0.2 (0.09)
95% C.I.		(-0.4, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.46
Analysis of Duration (days) on Ventilator through Day 90 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	214	218
n	214	218
LS Mean (SE)	0.4 (0.33)	0.0 (0.32)
95% C.I.	(-0.3, 1.0)	(-0.6, 0.6)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.4 (0.46)
95% C.I.		(-1.3, 0.5)
p-value		0.433
Corrected Hedge’s g (SE) [1]		-0.1 (0.10)
95% C.I.		(-0.3, 0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 32.54
Summary of Duration on Ventilator through Day 90 by Region

Region: Europe

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	15	14
Alive and never on ventilation [1]	15 (100%)	13 (93%)
On ventilation [2]	0	0
1 period	0	0
2 periods	0	0
>2 periods	0	0
Incomplete follow-up due to study withdrawal	0	1 (7%)
On ventilation prior to study withdrawal	0	0
Withdrawn and never on ventilation	0	1 (7%)
Incomplete follow-up due to death [3]	0	0
On ventilation prior to death	0	0
Deceased and never on ventilation	0	0
Ventilator use [3]		
0 days	15 (100%)	14 (100%)
1 - <=8 days	0	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.54
Summary of Duration on Ventilator through Day 90 by Region

Region: Europe

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.0	0.0
SD	0.00	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	0	0
Duration (days) - Subjects with event/death [3]		
n	0	0
Mean		
SD		
Median		
IQR		
Min.		
Max.		

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

Population: Intent-to-Treat

Table 32.54
Summary of Duration on Ventilator through Day 90 by Region

Region: North America

	Placebo (N=529)		Sotrovimab (500mg IV) (N=528)	
Number of subjects in subgroup	502		503	
Alive and never on ventilation [1]	485	(97%)	495	(98%)
On ventilation [2]	2	(<1%)	0	
1 period	2	(<1%)	0	
2 periods	0		0	
>2 periods	0		0	
Incomplete follow-up due to study withdrawal	13	(3%)	8	(2%)
On ventilation prior to study withdrawal	0		0	
Withdrawn and never on ventilation	13	(3%)	8	(2%)
Incomplete follow-up due to death [3]	3	(<1%)	0	
On ventilation prior to death	1	(<1%)	0	
Deceased and never on ventilation	2	(<1%)	0	
Ventilator use [3]				
0 days	498	(>99%)	503	(100%)
1 - <=8 days	0		0	
9 - <=15 days	1	(<1%)	0	
16 - <=22 days	0		0	
23 - <=29 days	0		0	
30 - <=59 days	0		0	
60 - <=90 days	3	(<1%)	0	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.54
Summary of Duration on Ventilator through Day 90 by Region

Region: North America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.5	0.0
SD	6.05	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	0
Duration (days) - Subjects with event/death [3]		
n	4	0
Mean	60.8	
SD	35.05	
Median	74.0	
IQR	40.0 - 81.5	
Min.	9	
Max.	86	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.54
Summary of Duration on Ventilator through Day 90 by Region

Region: South America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	12	11
Alive and never on ventilation [1]	10 (83%)	11 (100%)
On ventilation [2]	2 (17%)	0
1 period	2 (17%)	0
2 periods	0	0
>2 periods	0	0
Incomplete follow-up due to study withdrawal	0	0
On ventilation prior to study withdrawal	0	0
Withdrawn and never on ventilation	0	0
Incomplete follow-up due to death [3]	1 (8%)	0
On ventilation prior to death	1 (8%)	0
Deceased and never on ventilation	0	0
Ventilator use [3]		
0 days	10 (83%)	11 (100%)
1 - <=8 days	0	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	1 (8%)	0
60 - <=90 days	1 (8%)	0

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.54
Summary of Duration on Ventilator through Day 90 by Region

Region: South America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	10.4	0.0
SD	25.10	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	77	0
Duration (days) - Subjects with event/death [3]		
n	2	0
Mean	62.5	
SD	20.51	
Median	62.5	
IQR	48.0 - 77.0	
Min.	48	
Max.	77	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.55
Analysis of Duration (days) on Ventilator through Day 90 by Region

Region: Europe

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	15	14
n	15	14
LS Mean (SE)	0.0 (1.27)	0.0 (1.31)
95% C.I.	(-2.5, 2.5)	(-2.6, 2.6)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.0 (1.82)
95% C.I.		(-3.6, 3.6)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		0.0 (0.37)
95% C.I.		(-0.7, 0.7)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America) and treatment by region interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Table 32.55
Analysis of Duration (days) on Ventilator through Day 90 by Region

Region: North America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	502	503
n	502	503
LS Mean (SE)	0.5 (0.22)	0.0 (0.22)
95% C.I.	(0.1, 0.9)	(-0.4, 0.4)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.5 (0.31)
95% C.I.		(-1.1, 0.1)
p-value		0.118
Corrected Hedge’s g (SE) [1]		-0.1 (0.06)
95% C.I.		(-0.2, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America) and treatment by region interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 32.55
Analysis of Duration (days) on Ventilator through Day 90 by Region

Region: South America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	12	11
n	12	11
LS Mean (SE)	10.4 (1.42)	0.0 (1.48)
95% C.I.	(7.6, 13.2)	(-2.9, 2.9)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-10.4 (2.05)
95% C.I.		(-14.4, -6.4)
p-value		<0.001
Corrected Hedge’s g (SE) [1]		-2.0 (0.52)
95% C.I.		(-3.1, -1.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America) and treatment by region interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Table 22.18
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Age Group (<=70, >70)

Age group (years): <=70

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
	Number of subjects in subgroup		337	327
Day 8	Viral Load (log10 copies/mL)	n	281	277
		Mean	4.164	3.925
		SD	1.2811	1.1104
		Median	3.789	3.515
		Min.	2.873	2.873
		Max.	7.825	8.231
	Change from Baseline (log10 copies/mL)	n	281	277
		Mean	-2.532	-2.617
		SD	1.4015	1.3929
		Median	-2.521	-2.633
		Min.	-5.875	-5.981
		Max.	2.576	1.558

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Protocol: 214367
Population: Virology Data as of 27APR2021

Table 22.18
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Age Group (<=70, >70)

Age group (years): >70

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
	Number of subjects in subgroup		48	42
Day 8	Viral Load (log10 copies/mL)	n	42	39
		Mean	5.029	4.438
		SD	1.6585	1.6036
		Median	4.838	3.813
		Min.	2.873	2.873
		Max.	8.416	7.964
	Change from Baseline (log10 copies/mL)	n	42	39
		Mean	-1.855	-2.676
		SD	2.0067	1.8970
		Median	-2.115	-3.147
		Min.	-5.090	-5.238
		Max.	4.615	2.328

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Protocol: 214367
Population: Virology Data as of 27APR2021

Table 22.19
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Age Group (<=70, >70)

Age group (years): <=70

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	337	327
n	281	277
LS Mean (SE)	4.156 (0.0649)	3.968 (0.0655)
95% C.I.	(4.028, 4.283)	(3.840, 4.097)
LS Mean Change from Baseline (SE)	-2.511 (0.0649)	-2.699 (0.0655)
95% C.I.	(-2.639, -2.384)	(-2.828, -2.570)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.188 (0.0923)
95% C.I.		(-0.369, -0.007)
p-value		0.042
Corrected Hedge’s g (SE) [1]		-0.172 (0.0848)
95% C.I.		(-0.338, -0.006)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline and treatment by age interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Table 22.19
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Age Group (<=70, >70)

Age group (years): >70

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	48	42
n	42	39
LS Mean (SE)	4.941 (0.1679)	4.284 (0.1746)
95% C.I.	(4.611, 5.270)	(3.941, 4.627)
LS Mean Change from Baseline (SE)	-1.726 (0.1679)	-2.383 (0.1746)
95% C.I.	(-2.056, -1.397)	(-2.726, -2.040)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.656 (0.2421)
95% C.I.		(-1.132, -0.181)
p-value		0.007
Corrected Hedge’s g (SE) [1]		-0.597 (0.2273)
95% C.I.		(-1.042, -0.151)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline and treatment by age interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Protocol: 214367
Population: Virology Data as of 27APR2021

Table 22.20
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29
by Age Group (<=70, >70)

Age group (years): <=70

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	337	327
Negative SARS-CoV-2 viral load	233 (69%)	235 (72%)
Censored	104 (31%)	92 (28%)
VIR-7831 500mg vs. Placebo		
Inverse Hazard Ratio		1.02
95% C.I.		(0.85, 1.22)
p-value		0.857

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, age (<=70, >70 years old) and treatment by age interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

PPD

Protocol: 214367
Population: Virology Data as of 27APR2021

Table 22.20
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29
by Age Group (<=70, >70)

Age group (years): >70

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	48	42
Negative SARS-CoV-2 viral load	26 (54%)	28 (67%)
Censored	22 (46%)	14 (33%)
VIR-7831 500mg vs. Placebo		
Inverse Hazard Ratio		0.65
95% C.I.		(0.38, 1.12)
p-value		0.121

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, age (<=70, >70 years old) and treatment by age interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

PPD

Protocol: 214367
Population: Virology Data as of 27APR2021

Table 22.25
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
	Number of subjects in subgroup		84	72
Day 8	Viral Load (log10 copies/mL)	n	66	55
		Mean	3.371	3.139
		SD	1.0508	0.4851
		Median	2.873	2.873
		Min.	2.873	2.873
		Max.	8.416	5.073
	Change from Baseline (log10 copies/mL)	n	66	55
		Mean	-0.929	-1.023
		SD	1.1357	0.6106
		Median	-1.169	-1.009
		Min.	-2.118	-2.076
		Max.	4.615	0.426

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 22.25
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
	Number of subjects in subgroup		58	64
Day 8	Viral Load (log10 copies/mL)	n	50	59
		Mean	3.800	3.727
		SD	1.2792	1.2177
		Median	3.270	3.270
		Min.	2.873	2.873
		Max.	7.927	7.879
	Change from Baseline (log10 copies/mL)	n	50	59
		Mean	-1.766	-1.743
		SD	1.2639	1.1776
		Median	-2.278	-2.144
		Min.	-3.099	-3.042
		Max.	2.736	2.328

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 22.25
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
	Number of subjects in subgroup		60	74
Day 8	Viral Load (log10 copies/mL)	n	47	60
		Mean	4.158	3.803
		SD	1.1109	1.0344
		Median	4.005	3.315
		Min.	2.873	2.873
		Max.	7.165	7.877
	Change from Baseline (log10 copies/mL)	n	47	60
		Mean	-2.353	-2.698
		SD	1.1422	1.0844
		Median	-2.418	-2.970
		Min.	-3.997	-4.055
		Max.	0.517	1.653

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

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Table 22.25
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
	Number of subjects in subgroup		183	159
Day 8	Viral Load (log10 copies/mL)	n	160	142
		Mean	4.833	4.505
		SD	1.3158	1.1956
		Median	4.683	4.291
		Min.	2.873	2.873
		Max.	7.825	8.231
	Change from Baseline (log10 copies/mL)	n	160	142
		Mean	-3.307	-3.581
		SD	1.1647	1.1460
		Median	-3.431	-3.855
		Min.	-5.875	-5.981
		Max.	-0.169	-0.220

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 22.26
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	84	72
n	66	55
LS Mean (SE)	3.416 (0.1394)	3.173 (0.1527)
95% C.I.	(3.142, 3.690)	(2.873, 3.473)
LS Mean Change from Baseline (SE)	-0.903 (0.1369)	-1.004 (0.1500)
95% C.I.	(-1.172, -0.634)	(-1.299, -0.710)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.101 (0.2027)
95% C.I.		(-0.499, 0.297)
p-value		0.618
Corrected Hedge’s g (SE) [1]		-0.090 (0.1827)
95% C.I.		(-0.448, 0.268)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and treatment by baseline viral load category interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Table 22.26
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	58	64
n	50	59
LS Mean (SE)	3.791 (0.1600)	3.809 (0.1477)
95% C.I.	(3.477, 4.105)	(3.519, 4.100)
LS Mean Change from Baseline (SE)	-1.769 (0.1572)	-1.691 (0.1451)
95% C.I.	(-2.078, -1.460)	(-1.976, -1.406)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.078 (0.2139)
95% C.I.		(-0.342, 0.498)
p-value		0.715
Corrected Hedge’s g (SE) [1]		0.070 (0.1923)
95% C.I.		(-0.307, 0.446)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and treatment by baseline viral load category interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Table 22.26
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	60	74
n	47	60
LS Mean (SE)	4.185 (0.1651)	3.808 (0.1460)
95% C.I.	(3.861, 4.510)	(3.521, 4.094)
LS Mean Change from Baseline (SE)	-2.339 (0.1622)	-2.696 (0.1434)
95% C.I.	(-2.658, -2.021)	(-2.977, -2.414)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.356 (0.2166)
95% C.I.		(-0.782, 0.069)
p-value		0.100
Corrected Hedge’s g (SE) [1]		-0.318 (0.1960)
95% C.I.		(-0.703, 0.066)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and treatment by baseline viral load category interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Table 22.26
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	183	159
n	160	142
LS Mean (SE)	4.810 (0.0894)	4.454 (0.0956)
95% C.I.	(4.634, 4.985)	(4.267, 4.642)
LS Mean Change from Baseline (SE)	-3.321 (0.0878)	-3.609 (0.0940)
95% C.I.	(-3.494, -3.149)	(-3.794, -3.425)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.288 (0.1282)
95% C.I.		(-0.539, -0.036)
p-value		0.025
Corrected Hedge’s g (SE) [1]		-0.257 (0.1158)
95% C.I.		(-0.484, -0.030)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline viral load category and treatment by baseline viral load category interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Protocol: 214367
Population: Virology Data as of 27APR2021

Table 22.27
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	84	72
Negative SARS-CoV-2 viral load	79 (94%)	67 (93%)
Censored	5 (6%)	5 (7%)
VIR-7831 500mg vs. Placebo		
Inverse Hazard Ratio		1.01
95% C.I.		(0.73, 1.40)
p-value		0.955

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, baseline viral load category and treatment by baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

PPD

Table 22.27
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	58	64
Negative SARS-CoV-2 viral load	43 (74%)	48 (75%)
Censored	15 (26%)	16 (25%)
VIR-7831 500mg vs. Placebo		
Inverse Hazard Ratio		1.02
95% C.I.		(0.68, 1.54)
p-value		0.923

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, baseline viral load category and treatment by baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

PPD

Table 22.27
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	60	74
Negative SARS-CoV-2 viral load	39 (65%)	55 (74%)
Censored	21 (35%)	19 (26%)
VIR-7831 500mg vs. Placebo		
Inverse Hazard Ratio		0.98
95% C.I.		(0.65, 1.47)
p-value		0.909

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, baseline viral load category and treatment by baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

PPD

Table 22.27
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	183	159
Negative SARS-CoV-2 viral load	98 (54%)	93 (58%)
Censored	85 (46%)	66 (42%)
VIR-7831 500mg vs. Placebo		
Inverse Hazard Ratio		0.92
95% C.I.		(0.69, 1.22)
p-value		0.558

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, baseline viral load category and treatment by baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

PPD

Table 22.32
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Gender

Gender: Male

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
	Number of subjects in subgroup		190	174
Day 8	Viral Load (log10 copies/mL)	n	163	151
		Mean	4.304	4.023
		SD	1.4275	1.2417
		Median	3.789	3.522
		Min.	2.873	2.873
		Max.	7.825	8.231
	Change from Baseline (log10 copies/mL)	n	163	151
		Mean	-2.420	-2.527
		SD	1.4938	1.4998
		Median	-2.458	-2.512
		Min.	-5.875	-5.452
		Max.	2.576	2.328

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 22.32
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Gender

Gender: Female

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
	Number of subjects in subgroup		195	195
Day 8	Viral Load (log10 copies/mL)	n	160	165
		Mean	4.247	3.957
		SD	1.3013	1.1461
		Median	3.960	3.575
		Min.	2.873	2.873
		Max.	8.416	7.964
	Change from Baseline (log10 copies/mL)	n	160	165
		Mean	-2.468	-2.714
		SD	1.5257	1.4231
		Median	-2.414	-2.844
		Min.	-5.184	-5.981
		Max.	4.615	1.794

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Protocol: 214367
Population: Virology Data as of 27APR2021

Table 22.33
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Gender

Gender: Male

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	190	174
n	163	151
LS Mean (SE)	4.279 (0.0855)	4.074 (0.0888)
95% C.I.	(4.112, 4.447)	(3.900, 4.248)
LS Mean Change from Baseline (SE)	-2.388 (0.0855)	-2.593 (0.0888)
95% C.I.	(-2.556, -2.220)	(-2.767, -2.419)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.205 (0.1233)
95% C.I.		(-0.448, 0.037)
p-value		0.096
Corrected Hedge’s g (SE) [1]		-0.188 (0.1132)
95% C.I.		(-0.410, 0.034)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline and treatment by gender interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Table 22.33
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Gender

Gender: Female

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	195	195
n	160	165
LS Mean (SE)	4.235 (0.0864)	3.947 (0.0850)
95% C.I.	(4.065, 4.405)	(3.780, 4.114)
LS Mean Change from Baseline (SE)	-2.432 (0.0864)	-2.720 (0.0850)
95% C.I.	(-2.602, -2.263)	(-2.887, -2.553)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.288 (0.1214)
95% C.I.		(-0.526, -0.050)
p-value		0.018
Corrected Hedge’s g (SE) [1]		-0.263 (0.1114)
95% C.I.		(-0.482, -0.045)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline and treatment by gender interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Protocol: 214367
Population: Virology Data as of 27APR2021

Table 22.34
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Gender

Gender: Male

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	190	174
Negative SARS-CoV-2 viral load	125 (66%)	126 (72%)
Censored	65 (34%)	48 (28%)
VIR-7831 500mg vs. Placebo		
Inverse Hazard Ratio		0.86
95% C.I.		(0.67, 1.11)
p-value		0.252

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, gender (male, female) and treatment by gender interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

PPD

Table 22.34
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Gender

Gender: Female

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	195	195
Negative SARS-CoV-2 viral load	134 (69%)	137 (70%)
Censored	61 (31%)	58 (30%)
VIR-7831 500mg vs. Placebo		
Inverse Hazard Ratio		1.05
95% C.I.		(0.83, 1.34)
p-value		0.676

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, gender (male, female) and treatment by gender interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

PPD

Table 22.39
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Number of Risk Factors

Number of risk factors: <=1

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
	Number of subjects in subgroup		221	206
Day 8	Viral Load (log10 copies/mL)	n	187	176
		Mean	4.254	3.952
		SD	1.3496	1.0899
		Median	3.881	3.519
		Min.	2.873	2.873
		Max.	7.927	7.879
	Change from Baseline (log10 copies/mL)	n	187	176
		Mean	-2.513	-2.649
		SD	1.5158	1.4382
		Median	-2.521	-2.682
		Min.	-5.210	-5.981
		Max.	2.736	2.328

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 22.39
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Number of Risk Factors

Number of risk factors: 2

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
	Number of subjects in subgroup		113	124
Day 8	Viral Load (log10 copies/mL)	n	97	108
		Mean	4.259	4.043
		SD	1.3654	1.3139
		Median	3.890	3.595
		Min.	2.873	2.873
		Max.	8.416	8.231
	Change from Baseline (log10 copies/mL)	n	97	108
		Mean	-2.380	-2.502
		SD	1.5909	1.4840
		Median	-2.400	-2.589
		Min.	-5.875	-5.117
		Max.	4.615	1.794

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 22.39
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Number of Risk Factors

Number of risk factors: >=3

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
	Number of subjects in subgroup		51	39
Day 8	Viral Load (log10 copies/mL)	n	39	32
		Mean	4.427	4.010
		SD	1.4587	1.3181
		Median	4.090	3.510
		Min.	2.873	2.873
		Max.	7.796	7.964
	Change from Baseline (log10 copies/mL)	n	39	32
		Mean	-2.269	-2.907
		SD	1.2459	1.5075
		Median	-2.389	-2.882
		Min.	-4.554	-5.313
		Max.	-0.163	0.091

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 22.40
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8
by Number of Risk Factors

Number of risk factors: <=1

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	221	206
n	187	176
LS Mean (SE)	4.228 (0.0799)	3.997 (0.0825)
95% C.I.	(4.071, 4.385)	(3.835, 4.159)
LS Mean Change from Baseline (SE)	-2.439 (0.0799)	-2.670 (0.0825)
95% C.I.	(-2.596, -2.282)	(-2.832, -2.508)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.231 (0.1147)
95% C.I.		(-0.456, -0.005)
p-value		0.045
Corrected Hedge’s g (SE) [1]		-0.211 (0.1053)
95% C.I.		(-0.417, -0.004)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Table 22.40
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8
by Number of Risk Factors

Number of risk factors: 2

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	113	124
n	97	108
LS Mean (SE)	4.252 (0.1115)	4.074 (0.1053)
95% C.I.	(4.033, 4.471)	(3.867, 4.281)
LS Mean Change from Baseline (SE)	-2.415 (0.1115)	-2.593 (0.1053)
95% C.I.	(-2.634, -2.196)	(-2.800, -2.386)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.178 (0.1530)
95% C.I.		(-0.478, 0.123)
p-value		0.246
Corrected Hedge’s g (SE) [1]		-0.162 (0.1401)
95% C.I.		(-0.436, 0.113)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Table 22.40
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Number of Risk Factors

Number of risk factors: >=3

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	51	39
n	39	32
LS Mean (SE)	4.402 (0.1750)	3.851 (0.1946)
95% C.I.	(4.058, 4.746)	(3.469, 4.233)
LS Mean Change from Baseline (SE)	-2.265 (0.1750)	-2.816 (0.1946)
95% C.I.	(-2.609, -1.921)	(-3.198, -2.434)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.551 (0.2610)
95% C.I.		(-1.064, -0.039)
p-value		0.035
Corrected Hedge’s g (SE) [1]		-0.497 (0.2421)
95% C.I.		(-0.972, -0.023)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Protocol: 214367
Population: Virology Data as of 27APR2021

Table 22.41
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29
by Number of Risk Factors

Number of risk factors: <=1

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	221	206
Negative SARS-CoV-2 viral load	150 (68%)	142 (69%)
Censored	71 (32%)	64 (31%)
VIR-7831 500mg vs. Placebo		
Inverse Hazard Ratio		1.01
95% C.I.		(0.81, 1.28)
p-value		0.900

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

PPD

Table 22.41
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29
by Number of Risk Factors

Number of risk factors: 2

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	113	124
Negative SARS-CoV-2 viral load	75 (66%)	92 (74%)
Censored	38 (34%)	32 (26%)
VIR-7831 500mg vs. Placebo		
Inverse Hazard Ratio		0.96
95% C.I.		(0.70, 1.30)
p-value		0.774

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

PPD

Table 22.41
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29
by Number of Risk Factors

Number of risk factors: >=3

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	51	39
Negative SARS-CoV-2 viral load	34 (67%)	29 (74%)
Censored	17 (33%)	10 (26%)
VIR-7831 500mg vs. Placebo		
Inverse Hazard Ratio		0.70
95% C.I.		(0.43, 1.16)
p-value		0.167

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

PPD

Protocol: 214367
Population: Virology Data as of 27APR2021

Table 22.46
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
	Number of subjects in subgroup		166	167
Day 8	Viral Load (log10 copies/mL)	n	144	141
		Mean	4.213	4.125
		SD	1.3992	1.2881
		Median	3.716	3.747
		Min.	2.873	2.873
		Max.	8.416	8.231
	Change from Baseline (log10 copies/mL)	n	144	141
		Mean	-2.400	-2.516
		SD	1.5675	1.4467
		Median	-2.428	-2.532
		Min.	-5.276	-5.404
		Max.	4.615	2.328

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 22.46
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
	Number of subjects in subgroup		153	144
Day 8	Viral Load (log10 copies/mL)	n	129	125
		Mean	4.306	3.840
		SD	1.3384	1.0702
		Median	4.018	3.456
		Min.	2.873	2.873
		Max.	7.825	7.964
	Change from Baseline (log10 copies/mL)	n	129	125
		Mean	-2.476	-2.773
		SD	1.5345	1.4834
		Median	-2.552	-2.931
		Min.	-5.184	-5.981
		Max.	2.576	1.653

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 22.47
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8
by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	166	167
n	144	141
LS Mean (SE)	4.211 (0.0925)	4.101 (0.0934)
95% C.I.	(4.029, 4.393)	(3.917, 4.284)
LS Mean Change from Baseline (SE)	-2.449 (0.0925)	-2.560 (0.0934)
95% C.I.	(-2.631, -2.268)	(-2.743, -2.377)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.111 (0.1311)
95% C.I.		(-0.368, 0.147)
p-value		0.399
Corrected Hedge’s g (SE) [1]		-0.099 (0.1185)
95% C.I.		(-0.332, 0.133)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Protocol: 214367
Population: Virology Data as of 27APR2021

Table 22.47
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8
by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	153	144
n	129	125
LS Mean (SE)	4.285 (0.0978)	3.890 (0.0993)
95% C.I.	(4.093, 4.477)	(3.695, 4.086)
LS Mean Change from Baseline (SE)	-2.376 (0.0978)	-2.770 (0.0993)
95% C.I.	(-2.568, -2.184)	(-2.965, -2.575)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.394 (0.1390)
95% C.I.		(-0.668, -0.121)
p-value		0.005
Corrected Hedge’s g (SE) [1]		-0.354 (0.1265)
95% C.I.		(-0.602, -0.106)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Protocol: 214367
Population: Virology Data as of 27APR2021

Table 22.48
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29
by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	166	167
Negative SARS-CoV-2 viral load	104 (63%)	118 (71%)
Censored	62 (37%)	49 (29%)
VIR-7831 500mg vs. Placebo		
Inverse Hazard Ratio		0.87
95% C.I.		(0.67, 1.13)
p-value		0.288

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

PPD

Table 22.48
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29
by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	153	144
Negative SARS-CoV-2 viral load	112 (73%)	107 (74%)
Censored	41 (27%)	37 (26%)
VIR-7831 500mg vs. Placebo		
Inverse Hazard Ratio		0.97
95% C.I.		(0.75, 1.27)
p-value		0.835

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

PPD

Table 22.53
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Region

Region: Europe

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
	Number of subjects in subgroup		14	13
Day 8	Viral Load (log10 copies/mL)	n	12	13
		Mean	5.372	5.040
		SD	1.3719	1.1446
		Median	5.885	4.844
		Min.	3.270	3.270
		Max.	7.632	6.823
	Change from Baseline (log10 copies/mL)	n	12	13
		Mean	-2.416	-2.862
		SD	1.2529	1.3138
		Median	-2.647	-2.683
		Min.	-4.007	-5.313
		Max.	-0.152	-0.363

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 22.53
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Region

Region: North America

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
	Number of subjects in subgroup		361	346
Day 8	Viral Load (log10 copies/mL)	n	304	294
		Mean	4.214	3.929
		SD	1.3487	1.1749
		Median	3.820	3.457
		Min.	2.873	2.873
		Max.	8.416	8.231
	Change from Baseline (log10 copies/mL)	n	304	294
		Mean	-2.436	-2.612
		SD	1.5256	1.4681
		Median	-2.433	-2.685
		Min.	-5.875	-5.981
		Max.	4.615	2.328

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 22.53
Summary of Absolute and Change from Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Region

Region: South America

Visit			Placebo (N=385)	VIR-7831 500mg (N=369)
	Number of subjects in subgroup		10	10
Day 8	Viral Load (log10 copies/mL)	n	7	9
		Mean	5.087	4.418
		SD	1.1244	1.1043
		Median	5.361	4.075
		Min.	3.270	2.873
		Max.	6.581	6.865
	Change from Baseline (log10 copies/mL)	n	7	9
		Mean	-2.844	-2.683
		SD	1.1655	1.5543
		Median	-3.140	-2.633
		Min.	-4.359	-4.402
		Max.	-0.575	0.426

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 22.54
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Region

Region: Europe

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	14	13
n	12	13
LS Mean (SE)	4.932 (0.3164)	4.605 (0.3056)
95% C.I.	(4.310, 5.553)	(4.005, 5.205)
LS Mean Change from Baseline (SE)	-1.736 (0.3164)	-2.062 (0.3056)
95% C.I.	(-2.357, -1.114)	(-2.662, -1.462)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.327 (0.4375)
95% C.I.		(-1.186, 0.532)
p-value		0.455
Corrected Hedge’s g (SE) [1]		-0.287 (0.4024)
95% C.I.		(-1.076, 0.501)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline and treatment by region interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Table 22.54
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Region

Region: North America

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	361	346
n	304	294
LS Mean (SE)	4.219 (0.0626)	3.977 (0.0637)
95% C.I.	(4.096, 4.342)	(3.852, 4.102)
LS Mean Change from Baseline (SE)	-2.448 (0.0626)	-2.690 (0.0637)
95% C.I.	(-2.571, -2.325)	(-2.815, -2.565)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.242 (0.0893)
95% C.I.		(-0.417, -0.066)
p-value		0.007
Corrected Hedge’s g (SE) [1]		-0.221 (0.0820)
95% C.I.		(-0.382, -0.060)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline and treatment by region interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Table 22.54
Analysis of Change from Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Region

Region: South America

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	10	10
n	7	9
LS Mean (SE)	4.612 (0.4162)	4.278 (0.3655)
95% C.I.	(3.795, 5.429)	(3.560, 4.996)
LS Mean Change from Baseline (SE)	-2.055 (0.4162)	-2.389 (0.3655)
95% C.I.	(-2.872, -1.238)	(-3.107, -1.671)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.334 (0.5504)
95% C.I.		(-1.415, 0.747)
p-value		0.544
Corrected Hedge’s g (SE) [1]		-0.287 (0.5065)
95% C.I.		(-1.280, 0.705)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline and treatment by region interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Protocol: 214367
Population: Virology Data as of 27APR2021

Table 22.55
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Region

Region: Europe

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	14	13
Negative SARS-CoV-2 viral load	3 (21%)	5 (38%)
Censored	11 (79%)	8 (62%)
VIR-7831 500mg vs. Placebo		
Inverse Hazard Ratio		0.47
95% C.I.		(0.11, 1.98)
p-value		0.305

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, region (North America, Europe, South America) and treatment by region interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

PPD

Table 22.55
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Region

Region: North America

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	361	346
Negative SARS-CoV-2 viral load	255 (71%)	254 (73%)
Censored	106 (29%)	92 (27%)
VIR-7831 500mg vs. Placebo		
Inverse Hazard Ratio		1.00
95% C.I.		(0.84, 1.19)
p-value		>0.999

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, region (North America, Europe, South America) and treatment by region interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

PPD

Table 22.55
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Region

Region: South America

	Placebo (N=385)	VIR-7831 500mg (N=369)
Number of subjects in subgroup	10	10
Negative SARS-CoV-2 viral load	1 (10%)	4 (40%)
Censored	9 (90%)	6 (60%)
VIR-7831 500mg vs. Placebo		
Inverse Hazard Ratio		0.20
95% C.I.		(0.02, 1.76)
p-value		0.146

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, region (North America, Europe, South America) and treatment by region interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

PPD

Population: Intent-to-Treat

Table 32.6
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Age Group (<=70, >70)

Age group (years): <=70

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		473	472
Day 8	Viral Load (log10 copies/mL)	n	46	54
		Mean	2.682	2.676
		SD	0.0444	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.977	2.676
	Change from Baseline (log10 copies/mL)	n	18	18
		Mean	-0.053	-0.117
		SD	0.1230	0.1510
		Median	0.000	0.000
		Min.	-0.356	-0.301
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Population: Intent-to-Treat

Table 32.6
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Age Group (<=70, >70)

Age group (years): >70

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		56	56
Day 8	Viral Load (log10 copies/mL)	n	9	8
		Mean	2.743	2.676
		SD	0.1327	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.977	2.676
	Change from Baseline (log10 copies/mL)	n	2	4
		Mean	0.000	-0.301
		SD	0.0000	0.0000
		Median	0.000	-0.301
		Min.	0.000	-0.301
		Max.	0.000	-0.301

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Population: Intent-to-Treat

Table 32.7
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Age Group (<=70, >70)

Age group (years): <=70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	473	472
n	18	18
LS Mean (SE)	2.703 (0.0111)	2.676 (0.0109)
95% C.I.	(2.681, 2.726)	(2.653, 2.698)
LS Mean Change from Baseline (SE)	-0.089 (0.0111)	-0.116 (0.0109)
95% C.I.	(-0.111, -0.066)	(-0.138, -0.094)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.028 (0.0156)
95% C.I.		(-0.059, 0.004)
p-value		0.085
Corrected Hedge’s g (SE) [1]		-0.578 (0.3402)
95% C.I.		(-1.245, 0.089)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age group (<=70, >70 years old), baseline and treatment by age interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Population: Intent-to-Treat

Table 32.7
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Age Group (<=70, >70)

Age group (years): >70

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	56	56
n	2	4
LS Mean (SE)	2.818 (0.0328)	2.633 (0.0248)
95% C.I.	(2.752, 2.885)	(2.583, 2.683)
LS Mean Change from Baseline (SE)	0.027 (0.0328)	-0.159 (0.0248)
95% C.I.	(-0.040, 0.093)	(-0.209, -0.109)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.185 (0.0407)
95% C.I.		(-0.268, -0.103)
p-value		<0.001
Corrected Hedge’s g (SE) [1]		-3.042 (1.2333)
95% C.I.		(-5.459, -0.625)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age group (<=70, >70 years old), baseline and treatment by age interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Table 32.15
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		96	98
Day 8	Viral Load (log10 copies/mL)	n	16	11
		Mean	2.676	2.676
		SD	0.0000	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.676	2.676
	Change from Baseline (log10 copies/mL)	n	6	3
		Mean	0.000	0.000
		SD	0.0000	0.0000
		Median	0.000	0.000
		Min.	0.000	0.000
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Population: Intent-to-Treat

Table 32.15
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		84	72
Day 8	Viral Load (log10 copies/mL)	n	7	9
		Mean	2.676	2.676
		SD	0.0000	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.676	2.676
	Change from Baseline (log10 copies/mL)	n	3	1
		Mean	0.000	0.000
		SD	0.0000	
		Median	0.000	0.000
		Min.	0.000	0.000
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Population: Intent-to-Treat

Table 32.15
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		58	64
Day 8	Viral Load (log10 copies/mL)	n	4	7
		Mean	2.826	2.676
		SD	0.1738	0.0000
		Median	2.826	2.676
		Min.	2.676	2.676
		Max.	2.977	2.676
	Change from Baseline (log10 copies/mL)	n	3	2
		Mean	-0.119	-0.301
		SD	0.2057	0.0000
		Median	0.000	-0.301
		Min.	-0.356	-0.301
		Max.	0.000	-0.301

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Table 32.15
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		60	74
Day 8	Viral Load (log10 copies/mL)	n	8	7
		Mean	2.676	2.676
		SD	0.0000	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.676	2.676
	Change from Baseline (log10 copies/mL)	n	1	2
		Mean	0.000	0.000
		SD		0.0000
		Median	0.000	0.000
		Min.	0.000	0.000
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Population: Intent-to-Treat

Table 32.15
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		183	159
Day 8	Viral Load (log10 copies/mL)	n	14	20
		Mean	2.697	2.676
		SD	0.0805	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.977	2.676
	Change from Baseline (log10 copies/mL)	n	4	9
		Mean	-0.075	-0.234
		SD	0.1505	0.1327
		Median	0.000	-0.301
		Min.	-0.301	-0.301
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Table 32.16
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	96	98
n	6	3
LS Mean (SE)	2.716 (0.0239)	2.716 (0.0326)
95% C.I.	(2.666, 2.765)	(2.648, 2.783)
LS Mean Change from Baseline (SE)	-0.077 (0.0239)	-0.077 (0.0326)
95% C.I.	(-0.126, -0.028)	(-0.144, -0.009)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.000 (0.0384)
95% C.I.		(-0.079, 0.079)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		0.000 (0.7071)
95% C.I.		(-1.386, 1.386)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline nasal SARS-CoV-2 viral load category, baseline blood SARS-CoV-2 viral load and treatment by baseline nasal SARS-CoV-2 viral load category interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Table 32.16
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	84	72
n	3	1
LS Mean (SE)	2.716 (0.0326)	2.716 (0.0551)
95% C.I.	(2.648, 2.783)	(2.602, 2.829)
LS Mean Change from Baseline (SE)	-0.077 (0.0326)	-0.077 (0.0551)
95% C.I.	(-0.144, -0.009)	(-0.191, 0.037)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.000 (0.0628)
95% C.I.		(-0.130, 0.130)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		0.000 (1.1547)
95% C.I.		(-2.263, 2.263)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline nasal SARS-CoV-2 viral load category, baseline blood SARS-CoV-2 viral load and treatment by baseline nasal SARS-CoV-2 viral load category interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Population: Intent-to-Treat

Table 32.16
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
n	3	2
LS Mean (SE)	2.741 (0.0323)	2.613 (0.0409)
95% C.I.	(2.674, 2.808)	(2.528, 2.697)
LS Mean Change from Baseline (SE)	-0.051 (0.0323)	-0.180 (0.0409)
95% C.I.	(-0.118, 0.016)	(-0.264, -0.095)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.128 (0.0500)
95% C.I.		(-0.232, -0.025)
p-value		0.018
Corrected Hedge’s g (SE) [1]		-1.649 (1.0513)
95% C.I.		(-3.710, 0.412)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline nasal SARS-CoV-2 viral load category, baseline blood SARS-CoV-2 viral load and treatment by baseline nasal SARS-CoV-2 viral load category interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Table 32.16
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	60	74
n	1	2
LS Mean (SE)	2.716 (0.0551)	2.716 (0.0394)
95% C.I.	(2.602, 2.829)	(2.634, 2.797)
LS Mean Change from Baseline (SE)	-0.077 (0.0551)	-0.077 (0.0394)
95% C.I.	(-0.191, 0.037)	(-0.158, 0.005)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.000 (0.0666)
95% C.I.		(-0.138, 0.138)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		0.000 (1.2247)
95% C.I.		(-2.400, 2.400)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline nasal SARS-CoV-2 viral load category, baseline blood SARS-CoV-2 viral load and treatment by baseline nasal SARS-CoV-2 viral load category interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Population: Intent-to-Treat

Table 32.16
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	183	159
n	4	9
LS Mean (SE)	2.740 (0.0273)	2.636 (0.0202)
95% C.I.	(2.683, 2.796)	(2.594, 2.677)
LS Mean Change from Baseline (SE)	-0.053 (0.0273)	-0.157 (0.0202)
95% C.I.	(-0.109, 0.003)	(-0.198, -0.115)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.104 (0.0333)
95% C.I.		(-0.173, -0.035)
p-value		0.005
Corrected Hedge’s g (SE) [1]		-1.638 (0.6814)
95% C.I.		(-2.973, -0.302)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline nasal SARS-CoV-2 viral load category, baseline blood SARS-CoV-2 viral load and treatment by baseline nasal SARS-CoV-2 viral load category interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Population: Intent-to-Treat

Table 32.24
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Gender

Gender: Male

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		256	229
Day 8	Viral Load (log10 copies/mL)	n	28	23
		Mean	2.697	2.676
		SD	0.0789	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.977	2.676
	Change from Baseline (log10 copies/mL)	n	15	9
		Mean	-0.064	-0.167
		SD	0.1328	0.1587
		Median	0.000	-0.301
		Min.	-0.356	-0.301
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Table 32.24
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Gender

Gender: Female

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		273	299
Day 8	Viral Load (log10 copies/mL)	n	27	39
		Mean	2.687	2.676
		SD	0.0579	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.977	2.676
	Change from Baseline (log10 copies/mL)	n	5	13
		Mean	0.000	-0.139
		SD	0.0000	0.1562
		Median	0.000	0.000
		Min.	0.000	-0.301
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Population: Intent-to-Treat

Table 32.25
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Gender

Gender: Male

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	256	229
n	15	9
LS Mean (SE)	2.719 (0.0140)	2.665 (0.0182)
95% C.I.	(2.690, 2.747)	(2.628, 2.701)
LS Mean Change from Baseline (SE)	-0.073 (0.0140)	-0.127 (0.0182)
95% C.I.	(-0.102, -0.045)	(-0.164, -0.090)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.054 (0.0230)
95% C.I.		(-0.101, -0.007)
p-value		0.025
Corrected Hedge’s g (SE) [1]		-0.960 (0.4438)
95% C.I.		(-1.830, -0.090)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Population: Intent-to-Treat

Table 32.25
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Gender

Gender: Female

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	273	299
n	5	13
LS Mean (SE)	2.701 (0.0249)	2.671 (0.0150)
95% C.I.	(2.651, 2.752)	(2.640, 2.701)
LS Mean Change from Baseline (SE)	-0.091 (0.0249)	-0.121 (0.0150)
95% C.I.	(-0.141, -0.040)	(-0.151, -0.091)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.030 (0.0293)
95% C.I.		(-0.090, 0.029)
p-value		0.309
Corrected Hedge’s g (SE) [1]		-0.529 (0.5336)
95% C.I.		(-1.575, 0.517)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 32.33
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Number of Risk Factors

Number of risk factors: <=1

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		307	293
Day 8	Viral Load (log10 copies/mL)	n	36	29
		Mean	2.684	2.676
		SD	0.0502	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.977	2.676
	Change from Baseline (log10 copies/mL)	n	14	7
		Mean	-0.022	-0.215
		SD	0.0805	0.1469
		Median	0.000	-0.301
		Min.	-0.301	-0.301
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Table 32.33
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Number of Risk Factors

Number of risk factors: 2

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		153	178
Day 8	Viral Load (log10 copies/mL)	n	13	20
		Mean	2.722	2.676
		SD	0.1130	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.977	2.676
	Change from Baseline (log10 copies/mL)	n	4	10
		Mean	-0.164	-0.060
		SD	0.1911	0.1269
		Median	-0.151	0.000
		Min.	-0.356	-0.301
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Population: Intent-to-Treat

Table 32.33
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Number of Risk Factors

Number of risk factors: >=3

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		69	57
Day 8	Viral Load (log10 copies/mL)	n	6	13
		Mean	2.676	2.676
		SD	0.0000	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.676	2.676
	Change from Baseline (log10 copies/mL)	n	2	5
		Mean	0.000	-0.241
		SD	0.0000	0.1346
		Median	0.000	-0.301
		Min.	0.000	-0.301
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 32.34
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Number of Risk Factors

Number of risk factors: <=1

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	307	293
n	14	7
LS Mean (SE)	2.716 (0.0149)	2.650 (0.0211)
95% C.I.	(2.686, 2.746)	(2.608, 2.693)
LS Mean Change from Baseline (SE)	-0.076 (0.0149)	-0.141 (0.0211)
95% C.I.	(-0.106, -0.045)	(-0.184, -0.099)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.065 (0.0268)
95% C.I.		(-0.120, -0.011)
p-value		0.020
Corrected Hedge’s g (SE) [1]		-1.125 (0.4944)
95% C.I.		(-2.095, -0.156)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Table 32.34
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Number of Risk Factors

Number of risk factors: 2

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	153	178
n	4	10
LS Mean (SE)	2.719 (0.0277)	2.690 (0.0172)
95% C.I.	(2.663, 2.776)	(2.655, 2.725)
LS Mean Change from Baseline (SE)	-0.072 (0.0277)	-0.102 (0.0172)
95% C.I.	(-0.129, -0.016)	(-0.137, -0.067)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.029 (0.0334)
95% C.I.		(-0.097, 0.038)
p-value		0.386
Corrected Hedge’s g (SE) [1]		-0.502 (0.5992)
95% C.I.		(-1.677, 0.672)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Population: Intent-to-Treat

Table 32.34
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Number of Risk Factors

Number of risk factors: >=3

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	69	57
n	2	5
LS Mean (SE)	2.705 (0.0384)	2.644 (0.0251)
95% C.I.	(2.627, 2.783)	(2.593, 2.695)
LS Mean Change from Baseline (SE)	-0.086 (0.0384)	-0.148 (0.0251)
95% C.I.	(-0.164, -0.008)	(-0.199, -0.097)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.062 (0.0470)
95% C.I.		(-0.157, 0.034)
p-value		0.199
Corrected Hedge’s g (SE) [1]		-0.931 (0.8729)
95% C.I.		(-2.642, 0.780)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Population: Intent-to-Treat

Table 32.42
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		237	241
Day 8	Viral Load (log10 copies/mL)	n	25	21
		Mean	2.688	2.676
		SD	0.0602	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.977	2.676
	Change from Baseline (log10 copies/mL)	n	10	7
		Mean	-0.030	-0.043
		SD	0.0952	0.1138
		Median	0.000	0.000
		Min.	-0.301	-0.301
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Table 32.42
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		214	218
Day 8	Viral Load (log10 copies/mL)	n	23	30
		Mean	2.689	2.676
		SD	0.0628	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.977	2.676
	Change from Baseline (log10 copies/mL)	n	6	13
		Mean	0.000	-0.185
		SD	0.0000	0.1524
		Median	0.000	-0.301
		Min.	0.000	-0.301
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Population: Intent-to-Treat

Table 32.43
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	237	241
n	10	7
LS Mean (SE)	2.710 (0.0153)	2.683 (0.0184)
95% C.I.	(2.679, 2.742)	(2.645, 2.720)
LS Mean Change from Baseline (SE)	-0.057 (0.0153)	-0.085 (0.0184)
95% C.I.	(-0.088, -0.026)	(-0.122, -0.047)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.028 (0.0236)
95% C.I.		(-0.076, 0.021)
p-value		0.252
Corrected Hedge’s g (SE) [1]		-0.541 (0.5014)
95% C.I.		(-1.523, 0.442)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Population: Intent-to-Treat

Table 32.43
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	214	218
n	6	13
LS Mean (SE)	2.689 (0.0205)	2.662 (0.0147)
95% C.I.	(2.647, 2.731)	(2.632, 2.692)
LS Mean Change from Baseline (SE)	-0.079 (0.0205)	-0.105 (0.0147)
95% C.I.	(-0.121, -0.037)	(-0.135, -0.075)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.027 (0.0267)
95% C.I.		(-0.081, 0.028)
p-value		0.325
Corrected Hedge’s g (SE) [1]		-0.490 (0.4999)
95% C.I.		(-1.470, 0.490)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Population: Intent-to-Treat

Table 32.51
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Region

Region: Europe

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		15	14
Day 8	Viral Load (log10 copies/mL)	n	3	1
		Mean	2.676	2.676
		SD	0.0000	
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.676	2.676
	Change from Baseline (log10 copies/mL)	n	1	1
		Mean	-0.301	-0.301
		SD		
		Median	-0.301	-0.301
		Min.	-0.301	-0.301
		Max.	-0.301	-0.301

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Population: Intent-to-Treat

Table 32.51
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Region

Region: North America

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		502	503
Day 8	Viral Load (log10 copies/mL)	n	51	61
		Mean	2.688	2.676
		SD	0.0590	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.977	2.676
	Change from Baseline (log10 copies/mL)	n	18	21
		Mean	-0.017	-0.143
		SD	0.0710	0.1541
		Median	0.000	0.000
		Min.	-0.301	-0.301
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Population: Intent-to-Treat

Table 32.51
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Region

Region: South America

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		12	11
Day 8	Viral Load (log10 copies/mL)	n	1	0
		Mean	2.977	
		SD		
		Median	2.977	
		Min.	2.977	
		Max.	2.977	
	Change from Baseline (log10 copies/mL)	n	1	0
		Mean	-0.356	
		SD		
		Median	-0.356	
		Min.	-0.356	
		Max.	-0.356	

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

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Protocol: 214367
Population: Intent-to-Treat

Table 32.52
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Region

Region: Europe

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	15	14
n	1	1
LS Mean (SE)	2.652 (0.0470)	2.652 (0.0470)
95% C.I.	(2.557, 2.748)	(2.557, 2.748)
LS Mean Change from Baseline (SE)	-0.139 (0.0470)	-0.139 (0.0470)
95% C.I.	(-0.235, -0.044)	(-0.235, -0.044)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.000 (0.0647)
95% C.I.		(-0.131, 0.131)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		
95% C.I.		

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Table 32.52
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Region

Region: North America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	502	503
n	18	21
LS Mean (SE)	2.703 (0.0118)	2.672 (0.0101)
95% C.I.	(2.679, 2.727)	(2.652, 2.693)
LS Mean Change from Baseline (SE)	-0.089 (0.0118)	-0.119 (0.0101)
95% C.I.	(-0.113, -0.065)	(-0.140, -0.099)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.031 (0.0160)
95% C.I.		(-0.063, 0.002)
p-value		0.064
Corrected Hedge’s g (SE) [1]		-0.625 (0.3289)
95% C.I.		(-1.270, 0.020)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

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Population: Intent-to-Treat

Table 32.52
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Region

Region: South America

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	12	11
n	1	0
LS Mean (SE)	2.908 (0.0553)	
95% C.I.	(2.796, 3.020)	
LS Mean Change from Baseline (SE)	0.116 (0.0553)	
95% C.I.	(0.004, 0.229)	
Sotrovimab (500mg IV) vs. Placebo		
Corrected Hedge’s g (SE) [1]		
95% C.I.		

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.17
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Age Group (<=70, >70)

Age group (years): <=70

		Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup	473	472
Day 7	Number of subjects with event	27 (6%)	63 (13%)
	Number of subjects censored	3 (<1%)	5 (1%)
	Number of subjects without event	443 (94%)	404 (86%)
	Probability of having event [1]	5.7%	13.5%
	95% C.I.	(4.0%, 8.3%)	(10.7%, 16.9%)
Day 14	Number of subjects with event	93 (20%)	143 (30%)
	Number of subjects censored	4 (<1%)	5 (1%)
	Number of subjects without event	376 (79%)	324 (69%)
	Probability of having event [1]	19.8%	30.6%
	95% C.I.	(16.5%, 23.7%)	(26.6%, 35.0%)
Day 21	Number of subjects with event	159 (34%)	189 (40%)
	Number of subjects censored	314 (66%)	283 (60%)
	Number of subjects without event	0	0
	Probability of having event [1]	33.9%	40.5%
	95% C.I.	(29.8%, 38.4%)	(36.2%, 45.1%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, age (<=70, >70 years old) and treatment by age interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

PPD

Table 24.17
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Age Group (<=70, >70)

Age group (years): <=70

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		0.75
95% C.I.		(0.61, 0.93)
p-value		0.009

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, age (<=70, >70 years old) and treatment by age interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.17
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Age Group (<=70, >70)

Age group (years): >70

		Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup	56	56
Day 7	Number of subjects with event	4 (7%)	13 (23%)
	Number of subjects censored	1 (2%)	1 (2%)
	Number of subjects without event	51 (91%)	42 (75%)
	Probability of having event [1]	7.2%	23.6%
	95% C.I.	(2.8%, 18.2%)	(14.5%, 37.2%)
Day 14	Number of subjects with event	11 (20%)	21 (38%)
	Number of subjects censored	1 (2%)	1 (2%)
	Number of subjects without event	44 (79%)	34 (61%)
	Probability of having event [1]	20.0%	38.2%
	95% C.I.	(11.6%, 33.2%)	(26.8%, 52.3%)
Day 21	Number of subjects with event	19 (34%)	25 (45%)
	Number of subjects censored	37 (66%)	31 (55%)
	Number of subjects without event	0	0
	Probability of having event [1]	34.5%	45.5%
	95% C.I.	(23.6%, 48.6%)	(33.4%, 59.4%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, age (<=70, >70 years old) and treatment by age interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.17
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Age Group (<=70, >70)

Age group (years): >70

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		0.63
95% C.I.		(0.35, 1.14)
p-value		0.126

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, age (<=70, >70 years old) and treatment by age interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.18
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Age Group (<=70, >70)

Age group (years): <=70
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	473	472
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	159 (34%)	189 (40%)
Not sustained symptom alleviation	314 (66%)	283 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		0.75
95% C.I.		(0.57, 0.98)
p-value		0.035
Inverse Relative Risk [2]		0.84
95% C.I.		(0.71, 0.99)
p-value		0.036
Risk Difference (%) [3]		-6.43
95% C.I.		(-12.56, -0.29)
p-value		0.044

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and age by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.18
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Age Group (<=70, >70)

Age group (years): >70
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	56	56
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	19 (34%)	25 (45%)
Not sustained symptom alleviation	37 (66%)	31 (55%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		0.65
95% C.I.		(0.30, 1.41)
p-value		0.277
Inverse Relative Risk [2]		0.77
95% C.I.		(0.49, 1.24)
p-value		0.285
Risk Difference (%) [3]		-10.71
95% C.I.		(-28.69, 7.27)
p-value		0.334

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and age by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.19
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Age Group (<=70, >70)

Age group (years): <=70
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	473	472
FLU-PRO Plus Responder Status, n (%)		
Responder	215 (45%)	243 (51%)
Non-responder	98 (21%)	96 (20%)
Missing [1]	160 (34%)	133 (28%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.79
95% C.I.		(0.61, 1.01)
p-value		0.064
Inverse Relative Risk [3]		0.88
95% C.I.		(0.77, 1.01)
p-value		0.065
Risk Difference (%) [4]		-6.03
95% C.I.		(-12.39, 0.33)
p-value		0.069

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, age (<=70, >70 years old) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.19
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Age Group (<=70, >70)

Age group (years): >70
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	56	56
FLU-PRO Plus Responder Status, n (%)		
Responder	18 (32%)	22 (39%)
Non-responder	14 (25%)	18 (32%)
Missing [1]	24 (43%)	16 (29%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.73
95% C.I.		(0.34, 1.59)
p-value		0.431
Inverse Relative Risk [3]		0.82
95% C.I.		(0.50, 1.35)
p-value		0.433
Risk Difference (%) [4]		-7.14
95% C.I.		(-24.84, 10.56)
p-value		0.555

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, age (<=70, >70 years old) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.28
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

		Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup	96	98
Day 7	Number of subjects with event	6 (6%)	17 (17%)
	Number of subjects censored	0	0
	Number of subjects without event	90 (94%)	81 (83%)
	Probability of having event [1]	6.2%	17.3%
	95% C.I.	(2.9%, 13.4%)	(11.2%, 26.4%)
Day 14	Number of subjects with event	20 (21%)	33 (34%)
	Number of subjects censored	0	0
	Number of subjects without event	76 (79%)	65 (66%)
	Probability of having event [1]	20.8%	33.7%
	95% C.I.	(14.0%, 30.4%)	(25.3%, 43.9%)
Day 21	Number of subjects with event	31 (32%)	41 (42%)
	Number of subjects censored	65 (68%)	57 (58%)
	Number of subjects without event	0	0
	Probability of having event [1]	32.3%	41.8%
	95% C.I.	(23.9%, 42.6%)	(32.8%, 52.2%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, baseline viral load category and treatment by baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.28
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		0.68
95% C.I.		(0.43, 1.09)
p-value		0.107

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, baseline viral load category and treatment by baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.28
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

		Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup	84	72
Day 7	Number of subjects with event	7 (8%)	14 (19%)
	Number of subjects censored	0	0
	Number of subjects without event	77 (92%)	58 (81%)
	Probability of having event [1]	8.3%	19.4%
	95% C.I.	(4.1%, 16.7%)	(12.0%, 30.6%)
Day 14	Number of subjects with event	20 (24%)	33 (46%)
	Number of subjects censored	0	0
	Number of subjects without event	64 (76%)	39 (54%)
	Probability of having event [1]	23.8%	45.8%
	95% C.I.	(16.1%, 34.4%)	(35.2%, 58.0%)
Day 21	Number of subjects with event	39 (46%)	39 (54%)
	Number of subjects censored	45 (54%)	33 (46%)
	Number of subjects without event	0	0
	Probability of having event [1]	46.4%	54.2%
	95% C.I.	(36.5%, 57.6%)	(43.2%, 65.9%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, baseline viral load category and treatment by baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.28
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		0.70
95% C.I.		(0.45, 1.08)
p-value		0.109

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, baseline viral load category and treatment by baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.28
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

		Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup	58	64
Day 7	Number of subjects with event	6 (10%)	11 (17%)
	Number of subjects censored	0	1 (2%)
	Number of subjects without event	52 (90%)	52 (81%)
	Probability of having event [1]	10.3%	17.3%
	95% C.I.	(4.8%, 21.6%)	(10.0%, 29.1%)
Day 14	Number of subjects with event	18 (31%)	19 (30%)
	Number of subjects censored	0	1 (2%)
	Number of subjects without event	40 (69%)	44 (69%)
	Probability of having event [1]	31.0%	30.1%
	95% C.I.	(20.8%, 44.6%)	(20.3%, 43.0%)
Day 21	Number of subjects with event	30 (52%)	27 (42%)
	Number of subjects censored	28 (48%)	37 (58%)
	Number of subjects without event	0	0
	Probability of having event [1]	51.7%	43.0%
	95% C.I.	(39.7%, 65.0%)	(31.8%, 56.2%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, baseline viral load category and treatment by baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.28
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		1.20
95% C.I.		(0.71, 2.02)
p-value		0.489

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, baseline viral load category and treatment by baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.28
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

		Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup	60	74
Day 7	Number of subjects with event	4 (7%)	8 (11%)
	Number of subjects censored	0	1 (1%)
	Number of subjects without event	56 (93%)	65 (88%)
	Probability of having event [1]	6.7%	11.0%
	95% C.I.	(2.6%, 16.8%)	(5.6%, 20.7%)
Day 14	Number of subjects with event	14 (23%)	20 (27%)
	Number of subjects censored	1 (2%)	1 (1%)
	Number of subjects without event	45 (75%)	53 (72%)
	Probability of having event [1]	23.5%	27.4%
	95% C.I.	(14.7%, 36.5%)	(18.6%, 39.2%)
Day 21	Number of subjects with event	18 (30%)	28 (38%)
	Number of subjects censored	42 (70%)	46 (62%)
	Number of subjects without event	0	0
	Probability of having event [1]	30.3%	38.4%
	95% C.I.	(20.3%, 43.7%)	(28.3%, 50.5%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, baseline viral load category and treatment by baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.28
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		0.75
95% C.I.		(0.41, 1.36)
p-value		0.341

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, baseline viral load category and treatment by baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.28
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

		Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup	183	159
Day 7	Number of subjects with event	7 (4%)	12 (8%)
	Number of subjects censored	3 (2%)	0
	Number of subjects without event	173 (95%)	147 (92%)
	Probability of having event [1]	3.9%	7.5%
	95% C.I.	(1.9%, 8.0%)	(4.4%, 12.9%)
Day 14	Number of subjects with event	24 (13%)	33 (21%)
	Number of subjects censored	3 (2%)	0
	Number of subjects without event	156 (85%)	126 (79%)
	Probability of having event [1]	13.3%	20.8%
	95% C.I.	(9.1%, 19.2%)	(15.2%, 27.9%)
Day 21	Number of subjects with event	46 (25%)	49 (31%)
	Number of subjects censored	137 (75%)	110 (69%)
	Number of subjects without event	0	0
	Probability of having event [1]	25.7%	30.8%
	95% C.I.	(19.9%, 32.8%)	(24.3%, 38.6%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, baseline viral load category and treatment by baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.28
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		0.77
95% C.I.		(0.52, 1.16)
p-value		0.211

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, baseline viral load category and treatment by baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.29
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	96	98
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	31 (32%)	41 (42%)
Not sustained symptom alleviation	65 (68%)	57 (58%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		0.68
95% C.I.		(0.38, 1.22)
p-value		0.194
Inverse Relative Risk [2]		0.78
95% C.I.		(0.54, 1.14)
p-value		0.197
Risk Difference (%) [3]		-9.55
95% C.I.		(-23.07, 3.98)
p-value		0.184

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >=70 years old), baseline viral load category, gender (male, female) and baseline viral load category by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.

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Table 24.29
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	84	72
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	39 (46%)	39 (54%)
Not sustained symptom alleviation	45 (54%)	33 (46%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		0.73
95% C.I.		(0.39, 1.37)
p-value		0.328
Inverse Relative Risk [2]		0.86
95% C.I.		(0.63, 1.17)
p-value		0.329
Risk Difference (%) [3]		-7.74
95% C.I.		(-23.43, 7.95)
p-value		0.423

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >=70 years old), baseline viral load category, gender (male, female) and baseline viral load category by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.

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Table 24.29
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	58	64
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	30 (52%)	27 (42%)
Not sustained symptom alleviation	28 (48%)	37 (58%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		1.61
95% C.I.		(0.78, 3.33)
p-value		0.197
Inverse Relative Risk [2]		1.29
95% C.I.		(0.88, 1.88)
p-value		0.188
Risk Difference (%) [3]		9.54
95% C.I.		(-8.12, 27.19)
p-value		0.365

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >=70 years old), baseline viral load category, gender (male, female) and baseline viral load category by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.

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Table 24.29
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	60	74
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	18 (30%)	28 (38%)
Not sustained symptom alleviation	42 (70%)	46 (62%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		0.67
95% C.I.		(0.33, 1.40)
p-value		0.290
Inverse Relative Risk [2]		0.77
95% C.I.		(0.48, 1.25)
p-value		0.292
Risk Difference (%) [3]		-7.84
95% C.I.		(-23.86, 8.18)
p-value		0.366

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >=70 years old), baseline viral load category, gender (male, female) and baseline viral load category by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.

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Table 24.29
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	183	159
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	46 (25%)	49 (31%)
Not sustained symptom alleviation	137 (75%)	110 (69%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		0.73
95% C.I.		(0.45, 1.18)
p-value		0.206
Inverse Relative Risk [2]		0.80
95% C.I.		(0.57, 1.13)
p-value		0.211
Risk Difference (%) [3]		-5.68
95% C.I.		(-15.22, 3.86)
p-value		0.277

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >=70 years old), baseline viral load category, gender (male, female) and baseline viral load category by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.

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Table 24.30
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	96	98
FLU-PRO Plus Responder Status, n (%)		
Responder	40 (42%)	56 (57%)
Non-responder	24 (25%)	16 (16%)
Missing [1]	32 (33%)	26 (27%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.54
95% C.I.		(0.30, 0.95)
p-value		0.032
Inverse Relative Risk [3]		0.73
95% C.I.		(0.54, 0.98)
p-value		0.035
Risk Difference (%) [4]		-15.48
95% C.I.		(-29.38, -1.57)
p-value		0.033

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.30
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	84	72
FLU-PRO Plus Responder Status, n (%)		
Responder	43 (51%)	38 (53%)
Non-responder	17 (20%)	15 (21%)
Missing [1]	24 (29%)	19 (26%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.94
95% C.I.		(0.50, 1.76)
p-value		0.844
Inverse Relative Risk [3]		0.97
95% C.I.		(0.72, 1.31)
p-value		0.844
Risk Difference (%) [4]		-1.59
95% C.I.		(-17.31, 14.14)
p-value		0.874

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.30
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	58	64
FLU-PRO Plus Responder Status, n (%)		
Responder	28 (48%)	28 (44%)
Non-responder	12 (21%)	15 (23%)
Missing [1]	18 (31%)	21 (33%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.20
95% C.I.		(0.59, 2.45)
p-value		0.617
Inverse Relative Risk [3]		1.10
95% C.I.		(0.75, 1.62)
p-value		0.617
Risk Difference (%) [4]		4.53
95% C.I.		(-13.17, 22.22)
p-value		0.717

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.30
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	60	74
FLU-PRO Plus Responder Status, n (%)		
Responder	28 (47%)	36 (49%)
Non-responder	12 (20%)	17 (23%)
Missing [1]	20 (33%)	21 (28%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.92
95% C.I.		(0.47, 1.83)
p-value		0.820
Inverse Relative Risk [3]		0.96
95% C.I.		(0.67, 1.37)
p-value		0.820
Risk Difference (%) [4]		-1.98
95% C.I.		(-18.98, 15.02)
p-value		0.864

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.30
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	183	159
FLU-PRO Plus Responder Status, n (%)		
Responder	75 (41%)	72 (45%)
Non-responder	37 (20%)	43 (27%)
Missing [1]	71 (39%)	44 (28%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.84
95% C.I.		(0.55, 1.29)
p-value		0.424
Inverse Relative Risk [3]		0.91
95% C.I.		(0.71, 1.15)
p-value		0.423
Risk Difference (%) [4]		-4.30
95% C.I.		(-14.82, 6.22)
p-value		0.445

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.39
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Gender

Gender: Male

		Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup	256	229
Day 7	Number of subjects with event	22 (9%)	36 (16%)
	Number of subjects censored	2 (<1%)	2 (<1%)
	Number of subjects without event	232 (91%)	191 (83%)
	Probability of having event [1]	8.6%	15.8%
	95% C.I.	(5.8%, 12.8%)	(11.7%, 21.2%)
Day 14	Number of subjects with event	56 (22%)	76 (33%)
	Number of subjects censored	2 (<1%)	2 (<1%)
	Number of subjects without event	198 (77%)	151 (66%)
	Probability of having event [1]	22.0%	33.4%
	95% C.I.	(17.4%, 27.6%)	(27.7%, 40.0%)
Day 21	Number of subjects with event	92 (36%)	93 (41%)
	Number of subjects censored	164 (64%)	136 (59%)
	Number of subjects without event	0	0
	Probability of having event [1]	36.3%	41.0%
	95% C.I.	(30.7%, 42.5%)	(34.9%, 47.7%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, gender (male, female) and treatment by gender interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.39
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Gender

Gender: Male

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		0.79
95% C.I.		(0.59, 1.05)
p-value		0.109

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, gender (male, female) and treatment by gender interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.39
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Gender

Gender: Female

		Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup	273	299
Day 7	Number of subjects with event	9 (3%)	40 (13%)
	Number of subjects censored	2 (<1%)	4 (1%)
	Number of subjects without event	262 (96%)	255 (85%)
	Probability of having event [1]	3.3%	13.6%
	95% C.I.	(1.7%, 6.3%)	(10.1%, 18.0%)
Day 14	Number of subjects with event	48 (18%)	88 (29%)
	Number of subjects censored	3 (1%)	4 (1%)
	Number of subjects without event	222 (81%)	207 (69%)
	Probability of having event [1]	17.7%	29.8%
	95% C.I.	(13.7%, 22.8%)	(25.0%, 35.4%)
Day 21	Number of subjects with event	86 (32%)	121 (40%)
	Number of subjects censored	187 (68%)	178 (60%)
	Number of subjects without event	0	0
	Probability of having event [1]	31.9%	41.0%
	95% C.I.	(26.7%, 37.8%)	(35.7%, 46.9%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, gender (male, female) and treatment by gender interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.39
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Gender

Gender: Female

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		0.69
95% C.I.		(0.52, 0.91)
p-value		0.009

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, gender (male, female) and treatment by gender interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.40
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Gender

Gender: Male
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	256	229
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	92 (36%)	93 (41%)
Not sustained symptom alleviation	164 (64%)	136 (59%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		0.83
95% C.I.		(0.57, 1.20)
p-value		0.324
Inverse Relative Risk [2]		0.89
95% C.I.		(0.71, 1.12)
p-value		0.327
Risk Difference (%) [3]		-4.67
95% C.I.		(-13.33, 3.99)
p-value		0.305

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and gender by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.40
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Gender

Gender: Female
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	273	299
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	86 (32%)	121 (40%)
Not sustained symptom alleviation	187 (68%)	178 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		0.67
95% C.I.		(0.47, 0.94)
p-value		0.023
Inverse Relative Risk [2]		0.77
95% C.I.		(0.62, 0.97)
p-value		0.024
Risk Difference (%) [3]		-8.97
95% C.I.		(-16.80, -1.14)
p-value		0.030

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and gender by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.41
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Gender

Gender: Male
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	256	229
FLU-PRO Plus Responder Status, n (%)		
Responder	102 (40%)	116 (51%)
Non-responder	60 (23%)	47 (21%)
Missing [1]	94 (37%)	66 (29%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.65
95% C.I.		(0.45, 0.92)
p-value		0.018
Inverse Relative Risk [3]		0.79
95% C.I.		(0.65, 0.96)
p-value		0.018
Risk Difference (%) [4]		-10.81
95% C.I.		(-19.64, -1.99)
p-value		0.018

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.41
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Gender

Gender: Female
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	273	299
FLU-PRO Plus Responder Status, n (%)		
Responder	131 (48%)	149 (50%)
Non-responder	52 (19%)	67 (22%)
Missing [1]	90 (33%)	83 (28%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.93
95% C.I.		(0.67, 1.29)
p-value		0.659
Inverse Relative Risk [3]		0.96
95% C.I.		(0.81, 1.14)
p-value		0.660
Risk Difference (%) [4]		-1.85
95% C.I.		(-10.05, 6.35)
p-value		0.677

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.50
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Number of Risk Factors

Number of risk factors: <=1

		Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup	307	293
Day 7	Number of subjects with event	16 (5%)	39 (13%)
	Number of subjects censored	0	4 (1%)
	Number of subjects without event	291 (95%)	250 (85%)
	Probability of having event [1]	5.2%	13.5%
	95% C.I.	(3.2%, 8.4%)	(10.0%, 18.0%)
Day 14	Number of subjects with event	59 (19%)	89 (30%)
	Number of subjects censored	1 (<1%)	4 (1%)
	Number of subjects without event	247 (80%)	200 (68%)
	Probability of having event [1]	19.2%	30.8%
	95% C.I.	(15.3%, 24.1%)	(25.8%, 36.4%)
Day 21	Number of subjects with event	103 (34%)	116 (40%)
	Number of subjects censored	204 (66%)	177 (60%)
	Number of subjects without event	0	0
	Probability of having event [1]	33.6%	40.1%
	95% C.I.	(28.6%, 39.2%)	(34.7%, 46.0%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction term.

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Table 24.50
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Number of Risk Factors

Number of risk factors: <=1

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		0.75
95% C.I.		(0.58, 0.98)
p-value		0.035

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction term.

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Table 24.50
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Number of Risk Factors

Number of risk factors: 2

		Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup	153	178
Day 7	Number of subjects with event	10 (7%)	26 (15%)
	Number of subjects censored	4 (3%)	2 (1%)
	Number of subjects without event	139 (91%)	150 (84%)
	Probability of having event [1]	6.7%	14.8%
	95% C.I.	(3.7%, 12.1%)	(10.3%, 20.9%)
Day 14	Number of subjects with event	32 (21%)	56 (31%)
	Number of subjects censored	4 (3%)	2 (1%)
	Number of subjects without event	117 (76%)	120 (67%)
	Probability of having event [1]	21.5%	31.8%
	95% C.I.	(15.7%, 29.0%)	(25.5%, 39.3%)
Day 21	Number of subjects with event	55 (36%)	76 (43%)
	Number of subjects censored	98 (64%)	102 (57%)
	Number of subjects without event	0	0
	Probability of having event [1]	36.9%	43.2%
	95% C.I.	(29.7%, 45.2%)	(36.2%, 50.8%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction term.

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Table 24.50
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Number of Risk Factors

Number of risk factors: 2

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		0.77
95% C.I.		(0.54, 1.09)
p-value		0.136

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction term.

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Table 24.50
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Number of Risk Factors

Number of risk factors: >=3

		Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup	69	57
Day 7	Number of subjects with event	5 (7%)	11 (19%)
	Number of subjects censored	0	0
	Number of subjects without event	64 (93%)	46 (81%)
	Probability of having event [1]	7.2%	19.3%
	95% C.I.	(3.1%, 16.5%)	(11.2%, 32.1%)
Day 14	Number of subjects with event	13 (19%)	19 (33%)
	Number of subjects censored	0	0
	Number of subjects without event	56 (81%)	38 (67%)
	Probability of having event [1]	18.8%	33.3%
	95% C.I.	(11.4%, 30.2%)	(22.7%, 47.1%)
Day 21	Number of subjects with event	20 (29%)	22 (39%)
	Number of subjects censored	49 (71%)	35 (61%)
	Number of subjects without event	0	0
	Probability of having event [1]	29.4%	38.7%
	95% C.I.	(20.0%, 41.7%)	(27.5%, 52.7%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction term.

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Table 24.50
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Number of Risk Factors

Number of risk factors: >=3

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		0.65
95% C.I.		(0.35, 1.19)
p-value		0.162

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction term.

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Table 24.51
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Number of Risk Factors

Number of risk factors: <=1
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	307	293
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	103 (34%)	116 (40%)
Not sustained symptom alleviation	204 (66%)	177 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		0.77
95% C.I.		(0.55, 1.08)
p-value		0.131
Inverse Relative Risk [2]		0.85
95% C.I.		(0.69, 1.05)
p-value		0.133
Risk Difference (%) [3]		-6.04
95% C.I.		(-13.74, 1.66)
p-value		0.128

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.51
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Number of Risk Factors

Number of risk factors: 2
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	153	178
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	55 (36%)	76 (43%)
Not sustained symptom alleviation	98 (64%)	102 (57%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		0.75
95% C.I.		(0.48, 1.17)
p-value		0.198
Inverse Relative Risk [2]		0.84
95% C.I.		(0.64, 1.10)
p-value		0.199
Risk Difference (%) [3]		-6.75
95% C.I.		(-17.27, 3.77)
p-value		0.218

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.51
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Number of Risk Factors

Number of risk factors: >=3
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	69	57
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	20 (29%)	22 (39%)
Not sustained symptom alleviation	49 (71%)	35 (61%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		0.62
95% C.I.		(0.29, 1.31)
p-value		0.207
Inverse Relative Risk [2]		0.73
95% C.I.		(0.44, 1.20)
p-value		0.211
Risk Difference (%) [3]		-9.61
95% C.I.		(-26.17, 6.95)
p-value		0.263

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.52
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Number of Risk Factors

Number of risk factors: <=1
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	307	293
FLU-PRO Plus Responder Status, n (%)		
Responder	131 (43%)	140 (48%)
Non-responder	63 (21%)	63 (22%)
Missing [1]	113 (37%)	90 (31%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.81
95% C.I.		(0.59, 1.12)
p-value		0.209
Inverse Relative Risk [3]		0.89
95% C.I.		(0.75, 1.07)
p-value		0.209
Risk Difference (%) [4]		-5.11
95% C.I.		(-13.07, 2.85)
p-value		0.220

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.52
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Number of Risk Factors

Number of risk factors: 2
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	153	178
FLU-PRO Plus Responder Status, n (%)		
Responder	67 (44%)	97 (54%)
Non-responder	31 (20%)	40 (22%)
Missing [1]	55 (36%)	41 (23%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.65
95% C.I.		(0.42, 1.00)
p-value		0.053
Inverse Relative Risk [3]		0.80
95% C.I.		(0.64, 1.01)
p-value		0.056
Risk Difference (%) [4]		-10.70
95% C.I.		(-21.44, 0.04)
p-value		0.061

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.52
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Number of Risk Factors

Number of risk factors: >=3
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	69	57
FLU-PRO Plus Responder Status, n (%)		
Responder	35 (51%)	28 (49%)
Non-responder	18 (26%)	11 (19%)
Missing [1]	16 (23%)	18 (32%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.07
95% C.I.		(0.53, 2.15)
p-value		0.858
Inverse Relative Risk [3]		1.03
95% C.I.		(0.73, 1.47)
p-value		0.859
Risk Difference (%) [4]		1.60
95% C.I.		(-15.94, 19.14)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.61
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

		Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup	231	234
Day 7	Number of subjects with event	23 (10%)	51 (22%)
	Number of subjects censored	1 (<1%)	2 (<1%)
	Number of subjects without event	207 (90%)	181 (77%)
	Probability of having event [1]	10.0%	21.9%
	95% C.I.	(6.7%, 14.6%)	(17.1%, 27.8%)
Day 14	Number of subjects with event	57 (25%)	92 (39%)
	Number of subjects censored	2 (<1%)	2 (<1%)
	Number of subjects without event	172 (74%)	140 (60%)
	Probability of having event [1]	24.8%	39.6%
	95% C.I.	(19.7%, 30.9%)	(33.7%, 46.2%)
Day 21	Number of subjects with event	97 (42%)	122 (52%)
	Number of subjects censored	134 (58%)	112 (48%)
	Number of subjects without event	0	0
	Probability of having event [1]	42.5%	52.6%
	95% C.I.	(36.3%, 49.1%)	(46.3%, 59.1%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.61
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		0.69
95% C.I.		(0.53, 0.90)
p-value		0.007

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.61
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

		Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup	206	212
Day 7	Number of subjects with event	7 (3%)	22 (10%)
	Number of subjects censored	1 (<1%)	0
	Number of subjects without event	198 (96%)	190 (90%)
	Probability of having event [1]	3.4%	10.4%
	95% C.I.	(1.6%, 7.0%)	(7.0%, 15.3%)
Day 14	Number of subjects with event	33 (16%)	60 (28%)
	Number of subjects censored	1 (<1%)	0
	Number of subjects without event	172 (83%)	152 (72%)
	Probability of having event [1]	16.1%	28.3%
	95% C.I.	(11.7%, 21.9%)	(22.7%, 34.9%)
Day 21	Number of subjects with event	59 (29%)	73 (34%)
	Number of subjects censored	147 (71%)	139 (66%)
	Number of subjects without event	0	0
	Probability of having event [1]	28.8%	34.5%
	95% C.I.	(23.1%, 35.5%)	(28.5%, 41.3%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.61
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		0.75
95% C.I.		(0.53, 1.06)
p-value		0.102

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.62
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	231	234
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	97 (42%)	122 (52%)
Not sustained symptom alleviation	134 (58%)	112 (48%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		0.66
95% C.I.		(0.46, 0.95)
p-value		0.027
Inverse Relative Risk [2]		0.80
95% C.I.		(0.66, 0.98)
p-value		0.029
Risk Difference (%) [3]		-10.15
95% C.I.		(-19.17, -1.12)
p-value		0.033

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.62
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	206	212
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	59 (29%)	73 (34%)
Not sustained symptom alleviation	147 (71%)	139 (66%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		0.76
95% C.I.		(0.50, 1.16)
p-value		0.201
Inverse Relative Risk [2]		0.83
95% C.I.		(0.63, 1.10)
p-value		0.202
Risk Difference (%) [3]		-5.79
95% C.I.		(-14.68, 3.10)
p-value		0.209

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.63
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	231	234
FLU-PRO Plus Responder Status, n (%)		
Responder	85 (37%)	103 (44%)
Non-responder	93 (40%)	96 (41%)
Missing [1]	53 (23%)	35 (15%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.74
95% C.I.		(0.51, 1.07)
p-value		0.114
Inverse Relative Risk [3]		0.84
95% C.I.		(0.67, 1.04)
p-value		0.115
Risk Difference (%) [4]		-7.22
95% C.I.		(-16.12, 1.67)
p-value		0.131

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.63
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	206	212
FLU-PRO Plus Responder Status, n (%)		
Responder	148 (72%)	162 (76%)
Non-responder	18 (9%)	18 (8%)
Missing [1]	40 (19%)	32 (15%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.79
95% C.I.		(0.51, 1.22)
p-value		0.287
Inverse Relative Risk [3]		0.94
95% C.I.		(0.84, 1.05)
p-value		0.288
Risk Difference (%) [4]		-4.57
95% C.I.		(-12.96, 3.82)
p-value		0.316

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.72
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Region

Region: Europe

		Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup	15	14
Day 7	Number of subjects with event	2 (13%)	1 (7%)
	Number of subjects censored	0	1 (7%)
	Number of subjects without event	13 (87%)	12 (86%)
	Probability of having event [1]	13.3%	7.7%
	95% C.I.	(3.5%, 43.6%)	(1.1%, 43.4%)
Day 14	Number of subjects with event	2 (13%)	2 (14%)
	Number of subjects censored	0	1 (7%)
	Number of subjects without event	13 (87%)	11 (79%)
	Probability of having event [1]	13.3%	15.4%
	95% C.I.	(3.5%, 43.6%)	(4.1%, 48.8%)
Day 21	Number of subjects with event	3 (20%)	2 (14%)
	Number of subjects censored	12 (80%)	12 (86%)
	Number of subjects without event	0	0
	Probability of having event [1]	20.0%	15.4%
	95% C.I.	(6.9%, 50.0%)	(4.1%, 48.8%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, region (North America, Europe, South America) and treatment by region interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.72
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Region

Region: Europe

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		1.29
95% C.I.		(0.22, 7.74)
p-value		0.779

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, region (North America, Europe, South America) and treatment by region interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.72
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Region

Region: North America

		Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup	502	503
Day 7	Number of subjects with event	28 (6%)	74 (15%)
	Number of subjects censored	4 (<1%)	5 (<1%)
	Number of subjects without event	470 (94%)	424 (84%)
	Probability of having event [1]	5.6%	14.8%
	95% C.I.	(3.9%, 8.0%)	(12.0%, 18.3%)
Day 14	Number of subjects with event	100 (20%)	161 (32%)
	Number of subjects censored	5 (<1%)	5 (<1%)
	Number of subjects without event	397 (79%)	337 (67%)
	Probability of having event [1]	20.1%	32.3%
	95% C.I.	(16.8%, 23.9%)	(28.4%, 36.6%)
Day 21	Number of subjects with event	172 (34%)	211 (42%)
	Number of subjects censored	330 (66%)	292 (58%)
	Number of subjects without event	0	0
	Probability of having event [1]	34.6%	42.4%
	95% C.I.	(30.6%, 39.0%)	(38.2%, 46.8%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, region (North America, Europe, South America) and treatment by region interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.72
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Region

Region: North America

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		0.72
95% C.I.		(0.59, 0.88)
p-value		0.002

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, region (North America, Europe, South America) and treatment by region interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.72
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Region

Region: South America

		Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup	12	11
Day 7	Number of subjects with event	1 (8%)	1 (9%)
	Number of subjects censored	0	0
	Number of subjects without event	11 (92%)	10 (91%)
	Probability of having event [1]	8.3%	9.1%
	95% C.I.	(1.2%, 46.1%)	(1.3%, 49.2%)
Day 14	Number of subjects with event	2 (17%)	1 (9%)
	Number of subjects censored	0	0
	Number of subjects without event	10 (83%)	10 (91%)
	Probability of having event [1]	16.7%	9.1%
	95% C.I.	(4.4%, 51.8%)	(1.3%, 49.2%)
Day 21	Number of subjects with event	3 (25%)	1 (9%)
	Number of subjects censored	9 (75%)	10 (91%)
	Number of subjects without event	0	0
	Probability of having event [1]	25.0%	9.1%
	95% C.I.	(8.8%, 59.2%)	(1.3%, 49.2%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, region (North America, Europe, South America) and treatment by region interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.72
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Region

Region: South America

	Placebo (N=529)	VIR-7831 500mg (N=528)
VIR-7831 500 mg vs. Placebo		
Inverse Hazard Ratio		3.04
95% C.I.		(0.32, 29.20)
p-value		0.336

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, region (North America, Europe, South America) and treatment by region interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of VIR over Placebo.

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Table 24.73
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Region

Region: Europe
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	15	14
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	3 (20%)	2 (14%)
Not sustained symptom alleviation	12 (80%)	12 (86%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		1.40
95% C.I.		(0.20, 9.96)
p-value		0.738
Inverse Relative Risk [2]		1.34
95% C.I.		(0.26, 6.89)
p-value		0.726
Risk Difference (%) [3]		5.71
95% C.I.		(-21.59, 33.02)
p-value		>0.999

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and region by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.73
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Region

Region: North America
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	502	503
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	172 (34%)	211 (42%)
Not sustained symptom alleviation	330 (66%)	292 (58%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		0.72
95% C.I.		(0.55, 0.93)
p-value		0.012
Inverse Relative Risk [2]		0.81
95% C.I.		(0.70, 0.95)
p-value		0.012
Risk Difference (%) [3]		-7.69
95% C.I.		(-13.67, -1.70)
p-value		0.014

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and region by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.73
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Region

Region: South America
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	12	11
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	3 (25%)	1 (9%)
Not sustained symptom alleviation	9 (75%)	10 (91%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [1]		3.17
95% C.I.		(0.28, 36.39)
p-value		0.354
Inverse Relative Risk [2]		2.67
95% C.I.		(0.32, 22.44)
p-value		0.368
Risk Difference (%) [3]		15.91
95% C.I.		(-13.90, 45.72)
p-value		0.591

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female) and region by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.74
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Region

Region: Europe
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	15	14
FLU-PRO Plus Responder Status, n (%)		
Responder	3 (20%)	6 (43%)
Non-responder	2 (13%)	4 (29%)
Missing [1]	10 (67%)	4 (29%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.33
95% C.I.		(0.06, 1.73)
p-value		0.192
Inverse Relative Risk [3]		0.47
95% C.I.		(0.14, 1.52)
p-value		0.206
Risk Difference (%) [4]		-22.86
95% C.I.		(-55.75, 10.03)
p-value		0.246

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.74
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Region

Region: North America
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	502	503
FLU-PRO Plus Responder Status, n (%)		
Responder	229 (46%)	256 (51%)
Non-responder	107 (21%)	108 (21%)
Missing [1]	166 (33%)	139 (28%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.81
95% C.I.		(0.63, 1.04)
p-value		0.095
Inverse Relative Risk [3]		0.90
95% C.I.		(0.79, 1.02)
p-value		0.095
Risk Difference (%) [4]		-5.28
95% C.I.		(-11.45, 0.89)
p-value		0.101

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.74
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Region

Region: South America
Visit: Day 21

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	12	11
FLU-PRO Plus Responder Status, n (%)		
Responder	1 (8%)	3 (27%)
Non-responder	3 (25%)	2 (18%)
Missing [1]	8 (67%)	6 (55%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.24
95% C.I.		(0.02, 2.78)
p-value		0.255
Inverse Relative Risk [3]		0.31
95% C.I.		(0.04, 2.52)
p-value		0.271
Risk Difference (%) [4]		-18.94
95% C.I.		(-49.55, 11.67)
p-value		0.317

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.

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Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		473	472
Baseline	SF-12 Score	n	360	359
		Mean	57.37	58.84
		SD	33.306	33.376
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	230	220
		Mean	80.00	81.93
		SD	26.577	28.673
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	196	192
		Mean	19.71	23.31
		SD	35.639	38.208
		Median	16.98	25.00
		Min.	-75.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	360	359
		Mean	43.64	44.10
		SD	10.485	10.507
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	230	220
		Mean	50.76	51.37
		SD	8.366	9.026
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	196	192
		Mean	6.21	7.34
		SD	11.219	12.028
		Median	5.34	7.87
		Min.	-23.6	-31.5
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	359	359
		Mean	50.84	52.23
		SD	27.640	29.013
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	230	220
		Mean	77.45	81.25
		SD	24.367	25.523
		Median	75.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	196	192
		Mean	26.91	29.75
		SD	30.003	32.299
		Median	25.00	25.00
		Min.	-50.0	-62.5
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	359	359
		Mean	40.82	41.29
		SD	9.357	9.822
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	230	220
		Mean	49.83	51.11
		SD	8.247	8.639
		Median	49.00	57.46
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	196	192
		Mean	9.11	10.07
		SD	10.156	10.933
		Median	8.46	8.46
		Min.	-16.9	-21.2
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	358	359
		Mean	62.43	60.65
		SD	29.453	30.412
		Median	75.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	230	220
		Mean	86.63	89.09
		SD	21.993	21.509
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	196	192
		Mean	23.72	29.17
		SD	30.670	30.734
		Median	25.00	25.00
		Min.	-50.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	358	359
		Mean	44.18	43.53
		SD	10.626	10.971
		Median	48.71	39.69
		Min.	21.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	230	220
		Mean	52.91	53.79
		SD	7.934	7.760
		Median	57.73	57.73
		Min.	21.7	21.7
		Max.	57.7	57.7
	Change from Baseline	n	196	192
		Mean	8.56	10.52
		SD	11.065	11.088
		Median	9.02	9.02
		Min.	-18.0	-27.1
		Max.	36.1	36.1

Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	360	359
		Mean	56.68	54.83
		SD	28.562	29.013
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	230	220
		Mean	70.57	69.09
		SD	20.663	20.308
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	196	192
		Mean	11.48	13.75
		SD	25.280	31.648
		Median	0.00	0.00
		Min.	-60.0	-100.0
		Max.	85.0	85.0

Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	360	359
		Mean	46.43	45.70
		SD	11.354	11.534
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	230	220
		Mean	51.95	51.37
		SD	8.216	8.075
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
	Change from Baseline	n	196	192
		Mean	4.56	5.47
		SD	10.050	12.582
		Median	0.00	0.00
		Min.	-23.8	-39.8
		Max.	33.8	33.8

Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	359	359
		Mean	35.72	36.35
		SD	27.902	28.553
		Median	25.00	25.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	230	220
		Mean	59.89	65.80
		SD	31.906	32.896
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	196	192
		Mean	25.89	28.26
		SD	31.661	39.786
		Median	25.00	25.00
		Min.	-50.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	359	359
		Mean	43.45	43.70
		SD	10.980	11.236
		Median	39.23	39.23
		Min.	29.4	29.4
		Max.	68.7	68.7
Day 29	SF-12 Score	n	230	220
		Mean	52.96	55.28
		SD	12.554	12.943
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	196	192
		Mean	10.19	11.12
		SD	12.458	15.655
		Median	9.84	9.84
		Min.	-19.7	-39.3
		Max.	39.3	39.3

Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	359	359
		Mean	46.31	45.19
		SD	36.213	36.275
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	230	220
		Mean	81.41	85.68
		SD	26.734	26.162
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	196	192
		Mean	35.08	41.15
		SD	38.446	40.607
		Median	50.00	50.00
		Min.	-50.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	359	359
		Mean	37.80	37.40
		SD	12.885	12.907
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	230	220
		Mean	50.29	51.81
		SD	9.511	9.308
		Median	56.90	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	196	192
		Mean	12.48	14.64
		SD	13.678	14.448
		Median	17.79	17.79
		Min.	-17.8	-26.7
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	359	359
		Mean	64.73	66.75
		SD	27.862	29.222
		Median	62.50	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	230	220
		Mean	83.91	87.78
		SD	23.262	22.710
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	196	192
		Mean	18.69	21.42
		SD	27.430	31.348
		Median	12.50	25.00
		Min.	-50.0	-62.5
		Max.	87.5	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	359	359
		Mean	41.61	42.45
		SD	11.586	12.151
		Median	40.69	45.89
		Min.	14.7	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	230	220
		Mean	49.59	51.20
		SD	9.672	9.443
		Median	56.28	56.28
		Min.	14.7	14.7
		Max.	56.3	56.3
	Change from Baseline	n	196	192
		Mean	7.77	8.91
		SD	11.406	13.035
		Median	5.20	10.39
		Min.	-20.8	-26.0
		Max.	36.4	41.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	359	359
		Mean	58.46	58.84
		SD	22.370	23.786
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	230	220
		Mean	74.51	78.24
		SD	22.328	21.002
		Median	75.00	87.50
		Min.	12.5	25.0
		Max.	100.0	100.0
	Change from Baseline	n	196	192
		Mean	16.01	21.09
		SD	25.626	29.686
		Median	12.50	12.50
		Min.	-37.5	-50.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	359	359
		Mean	45.15	45.32
		SD	10.266	10.915
		Median	41.26	41.26
		Min.	18.3	18.3
		Max.	64.2	64.2
Day 29	SF-12 Score	n	230	220
		Mean	52.51	54.22
		SD	10.247	9.639
		Median	52.74	58.47
		Min.	24.1	29.8
		Max.	64.2	64.2
	Change from Baseline	n	196	192
		Mean	7.35	9.68
		SD	11.761	13.623
		Median	5.74	5.74
		Min.	-17.2	-23.0
		Max.	34.4	45.9

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	359	359
		Mean	43.92	43.71
		SD	9.139	9.023
		Median	43.93	43.93
		Min.	17.4	20.2
		Max.	62.6	64.6
Day 29	SF-12 Score	n	230	220
		Mean	51.28	51.49
		SD	7.211	7.695
		Median	52.78	53.65
		Min.	22.7	23.6
		Max.	65.3	69.4
	Change from Baseline	n	196	192
		Mean	6.77	7.72
		SD	8.791	9.289
		Median	5.52	7.88
		Min.	-13.3	-19.7
		Max.	35.6	30.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	359	359
		Mean	42.40	42.71
		SD	9.971	10.287
		Median	42.18	41.76
		Min.	13.8	11.0
		Max.	70.0	65.0
Day 29	SF-12 Score	n	230	220
		Mean	51.35	53.46
		SD	10.037	8.874
		Median	53.21	55.38
		Min.	16.0	20.4
		Max.	65.6	65.0
	Change from Baseline	n	196	192
		Mean	9.24	11.08
		SD	10.856	12.431
		Median	7.66	11.57
		Min.	-18.4	-20.6
		Max.	45.3	43.7

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	358	359
		Mean	0.642	0.640
		SD	0.1222	0.1320
		Median	0.626	0.618
		Min.	0.35	0.35
		Max.	1.00	1.00
Day 29	SF-12 Score	n	230	220
		Mean	0.797	0.838
		SD	0.1477	0.1498
		Median	0.800	0.860
		Min.	0.41	0.43
		Max.	1.00	1.00
	Change from Baseline	n	196	192
		Mean	0.159	0.199
		SD	0.1569	0.1830
		Median	0.140	0.202
		Min.	-0.26	-0.31
		Max.	0.52	0.66

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	359	359
		Mean	48.83	49.08
		SD	26.546	28.159
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	230	220
		Mean	78.94	82.81
		SD	22.575	23.813
		Median	87.50	93.75
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	196	192
		Mean	30.26	34.70
		SD	27.540	30.590
		Median	28.13	40.63
		Min.	-43.8	-56.3
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	359	359
		Mean	38.77	38.86
		SD	9.537	10.117
		Median	39.19	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 29	SF-12 Score	n	230	220
		Mean	49.59	50.98
		SD	8.112	8.557
		Median	52.66	54.91
		Min.	21.2	21.2
		Max.	57.2	57.2
	Change from Baseline	n	196	192
		Mean	10.87	12.47
		SD	9.895	10.991
		Median	10.10	14.59
		Min.	-15.7	-20.2
		Max.	35.9	35.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	359	359
		Mean	40.37	40.58
		SD	24.518	24.815
		Median	43.75	43.75
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	230	220
		Mean	67.45	71.96
		SD	25.466	25.421
		Median	68.75	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	196	192
		Mean	28.76	32.03
		SD	24.859	28.819
		Median	31.25	34.38
		Min.	-31.3	-50.0
		Max.	93.8	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	359	359
		Mean	42.08	42.18
		SD	11.655	11.796
		Median	43.69	43.69
		Min.	22.9	22.9
		Max.	70.4	70.4
Day 29	SF-12 Score	n	230	220
		Mean	54.95	57.09
		SD	12.103	12.082
		Median	55.57	58.54
		Min.	22.9	22.9
		Max.	70.4	70.4
	Change from Baseline	n	196	192
		Mean	13.67	15.22
		SD	11.816	13.698
		Median	14.85	16.34
		Min.	-14.9	-23.8
		Max.	44.6	47.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		56	56
Baseline	SF-12 Score	n	39	40
		Mean	46.15	43.13
		SD	34.669	27.728
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	27	21
		Mean	72.22	70.24
		SD	29.689	30.227
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	19	17
		Mean	21.05	23.53
		SD	40.193	34.765
		Median	0.00	25.00
		Min.	-25.0	-25.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	40.11	39.16
		SD	10.914	8.729
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	27	21
		Mean	48.32	47.69
		SD	9.346	9.516
		Median	49.19	49.19
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	19	17
		Mean	6.63	7.41
		SD	12.653	10.944
		Median	0.00	7.87
		Min.	-7.9	-7.9
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	46.79	55.00
		SD	26.705	25.445
		Median	50.00	50.00
		Min.	0.0	12.5
		Max.	100.0	100.0
Day 29	SF-12 Score	n	27	21
		Mean	70.37	73.21
		SD	28.197	27.468
		Median	75.00	75.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	19	17
		Mean	23.03	19.12
		SD	33.918	36.475
		Median	25.00	12.50
		Min.	-50.0	-50.0
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	39.45	42.23
		SD	9.041	8.614
		Median	40.54	40.54
		Min.	23.6	27.8
		Max.	57.5	57.5
Day 29	SF-12 Score	n	27	21
		Mean	47.43	48.39
		SD	9.545	9.297
		Median	49.00	49.00
		Min.	32.1	23.6
		Max.	57.5	57.5
	Change from Baseline	n	19	17
		Mean	7.79	6.47
		SD	11.483	12.348
		Median	8.46	4.23
		Min.	-16.9	-16.9
		Max.	25.4	25.4

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	60.26	61.88
		SD	27.932	27.144
		Median	50.00	62.50
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	27	21
		Mean	77.78	84.52
		SD	27.151	23.017
		Median	75.00	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	19	17
		Mean	19.74	8.82
		SD	24.408	33.002
		Median	25.00	25.00
		Min.	0.0	-50.0
		Max.	75.0	50.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	43.39	43.97
		SD	10.077	9.793
		Median	39.69	44.20
		Min.	21.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	27	21
		Mean	49.71	52.15
		SD	9.795	8.304
		Median	48.71	57.73
		Min.	21.7	30.7
		Max.	57.7	57.7
	Change from Baseline	n	19	17
		Mean	7.12	3.18
		SD	8.806	11.907
		Median	9.02	9.02
		Min.	0.0	-18.0
		Max.	27.1	18.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	47.95	46.38
		SD	24.487	30.863
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	27	21
		Mean	73.52	64.05
		SD	18.903	20.834
		Median	60.00	60.00
		Min.	25.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	19	17
		Mean	29.74	11.18
		SD	22.141	31.797
		Median	35.00	0.00
		Min.	0.0	-35.0
		Max.	75.0	60.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	42.96	42.34
		SD	9.734	12.270
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	27	21
		Mean	53.13	49.36
		SD	7.517	8.282
		Median	47.75	47.75
		Min.	33.8	33.8
		Max.	63.7	63.7
	Change from Baseline	n	19	17
		Mean	11.82	4.44
		SD	8.802	12.639
		Median	13.91	0.00
		Min.	0.0	-13.9
		Max.	29.8	23.9

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	42.95	37.50
		SD	27.475	21.926
		Median	50.00	37.50
		Min.	0.0	0.0
		Max.	100.0	75.0
Day 29	SF-12 Score	n	27	20
		Mean	61.11	73.75
		SD	29.689	27.476
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	19	17
		Mean	18.42	32.35
		SD	34.199	27.620
		Median	25.00	25.00
		Min.	-50.0	0.0
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	46.29	44.15
		SD	10.811	8.628
		Median	49.07	44.15
		Min.	29.4	29.4
		Max.	68.7	58.9
Day 29	SF-12 Score	n	27	20
		Mean	53.44	58.41
		SD	11.681	10.810
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	19	17
		Mean	7.25	12.73
		SD	13.457	10.867
		Median	9.83	9.84
		Min.	-19.7	0.0
		Max.	29.5	29.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	53.21	60.63
		SD	33.037	29.897
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	27	21
		Mean	75.00	89.29
		SD	25.944	16.903
		Median	75.00	100.00
		Min.	25.0	50.0
		Max.	100.0	100.0
	Change from Baseline	n	19	17
		Mean	13.16	19.12
		SD	44.385	32.511
		Median	25.00	25.00
		Min.	-75.0	-50.0
		Max.	100.0	50.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	40.25	42.89
		SD	11.754	10.637
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	27	21
		Mean	48.01	53.09
		SD	9.229	6.013
		Median	48.01	56.90
		Min.	30.2	39.1
		Max.	56.9	56.9
	Change from Baseline	n	19	17
		Mean	4.68	6.80
		SD	15.791	11.568
		Median	8.90	8.90
		Min.	-26.7	-17.8
		Max.	35.6	17.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	66.03	68.75
		SD	29.097	28.022
		Median	50.00	68.75
		Min.	12.5	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	27	21
		Mean	83.80	88.69
		SD	23.466	18.073
		Median	100.00	100.00
		Min.	25.0	50.0
		Max.	100.0	100.0
	Change from Baseline	n	19	17
		Mean	9.87	19.12
		SD	34.756	33.400
		Median	0.00	12.50
		Min.	-75.0	-50.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	42.15	43.29
		SD	12.100	11.653
		Median	35.49	43.29
		Min.	19.9	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	27	21
		Mean	49.54	51.58
		SD	9.758	7.514
		Median	56.28	56.28
		Min.	25.1	35.5
		Max.	56.3	56.3
	Change from Baseline	n	19	17
		Mean	4.10	7.95
		SD	14.454	13.888
		Median	0.00	5.20
		Min.	-31.2	-20.8
		Max.	31.2	41.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	58.01	62.19
		SD	24.076	23.934
		Median	50.00	56.25
		Min.	25.0	25.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	27	21
		Mean	75.93	78.57
		SD	20.489	25.355
		Median	75.00	87.50
		Min.	37.5	12.5
		Max.	100.0	100.0
	Change from Baseline	n	19	17
		Mean	19.08	17.65
		SD	30.153	29.666
		Median	25.00	12.50
		Min.	-37.5	-25.0
		Max.	75.0	62.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	44.94	46.86
		SD	11.049	10.984
		Median	41.26	44.13
		Min.	29.8	29.8
		Max.	64.2	64.2
Day 29	SF-12 Score	n	27	21
		Mean	53.16	54.38
		SD	9.403	11.635
		Median	52.74	58.47
		Min.	35.5	24.1
		Max.	64.2	64.2
	Change from Baseline	n	19	17
		Mean	8.76	8.10
		SD	13.839	13.615
		Median	11.47	5.74
		Min.	-17.2	-11.5
		Max.	34.4	28.7

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	40.84	40.72
		SD	8.540	7.414
		Median	40.46	40.79
		Min.	19.3	24.0
		Max.	58.2	57.3
Day 29	SF-12 Score	n	27	21
		Mean	48.58	47.90
		SD	8.214	9.995
		Median	50.16	49.75
		Min.	28.3	23.5
		Max.	58.4	61.7
	Change from Baseline	n	19	17
		Mean	8.21	4.53
		SD	9.694	9.797
		Median	6.90	3.78
		Min.	-8.8	-15.0
		Max.	26.0	21.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	44.97	46.43
		SD	10.422	10.509
		Median	41.40	46.48
		Min.	28.9	27.1
		Max.	73.0	69.3
Day 29	SF-12 Score	n	27	21
		Mean	52.29	55.93
		SD	8.269	9.195
		Median	53.10	60.06
		Min.	34.9	35.5
		Max.	62.6	66.8
	Change from Baseline	n	19	17
		Mean	5.63	9.33
		SD	13.532	12.870
		Median	5.38	7.89
		Min.	-12.9	-15.3
		Max.	33.5	24.2

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	0.655	0.655
		SD	0.1234	0.1167
		Median	0.615	0.638
		Min.	0.47	0.44
		Max.	0.92	0.92
Day 29	SF-12 Score	n	27	20
		Mean	0.751	0.810
		SD	0.1498	0.1587
		Median	0.708	0.828
		Min.	0.51	0.51
		Max.	1.00	1.00
	Change from Baseline	n	19	17
		Mean	0.078	0.132
		SD	0.1712	0.1916
		Median	0.045	0.140
		Min.	-0.23	-0.14
		Max.	0.52	0.39

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	47.60	53.91
		SD	24.778	24.379
		Median	43.75	50.00
		Min.	0.0	6.3
		Max.	100.0	100.0
Day 29	SF-12 Score	n	27	21
		Mean	70.14	78.87
		SD	29.178	22.834
		Median	75.00	87.50
		Min.	12.5	25.0
		Max.	100.0	100.0
	Change from Baseline	n	19	17
		Mean	21.71	22.06
		SD	35.070	34.454
		Median	25.00	18.75
		Min.	-56.3	-37.5
		Max.	81.3	87.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	38.33	40.59
		SD	8.901	8.759
		Median	36.95	39.19
		Min.	21.2	23.5
		Max.	57.2	57.2
Day 29	SF-12 Score	n	27	21
		Mean	46.43	49.56
		SD	10.484	8.205
		Median	48.17	52.66
		Min.	25.7	30.2
		Max.	57.2	57.2
	Change from Baseline	n	19	17
		Mean	7.80	7.93
		SD	12.600	12.379
		Median	8.98	6.74
		Min.	-20.2	-13.5
		Max.	29.2	31.4

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	44.71	44.06
		SD	20.904	22.242
		Median	43.75	50.00
		Min.	0.0	0.0
		Max.	87.5	93.8
Day 29	SF-12 Score	n	27	21
		Mean	63.66	77.18
		SD	24.639	19.725
		Median	62.50	75.00
		Min.	0.0	31.3
		Max.	100.0	100.0
	Change from Baseline	n	19	17
		Mean	18.75	32.72
		SD	32.073	29.276
		Median	18.75	25.00
		Min.	-50.0	-6.3
		Max.	75.0	93.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.22
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	39	40
		Mean	44.14	43.84
		SD	9.937	10.573
		Median	43.69	46.66
		Min.	22.9	22.9
		Max.	64.5	67.5
Day 29	SF-12 Score	n	27	21
		Mean	53.15	59.58
		SD	11.711	9.375
		Median	52.60	58.54
		Min.	22.9	37.7
		Max.	70.4	70.4
	Change from Baseline	n	19	17
		Mean	8.91	15.55
		SD	15.244	13.916
		Median	8.91	11.89
		Min.	-23.8	-3.0
		Max.	35.7	44.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	473	472
n	196	192
LS Mean (SE)	81.33 (1.915)	81.81 (1.931)
95% C.I.	(77.57, 85.10)	(78.01, 85.60)
LS Mean Change from Baseline (SE)	22.23 (1.915)	22.70 (1.931)
95% C.I.	(18.46, 25.99)	(18.90, 26.49)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.47 (2.721)
95% C.I.		(-4.88, 5.82)
p-value		0.862
Corrected Hedge’s g (SE) [1]		0.02 (0.102)
95% C.I.		(-0.18, 0.22)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Role Physical (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	196	192
LS Mean (SE)	78.77 (1.729)	81.01 (1.747)
95% C.I.	(75.37, 82.17)	(77.58, 84.45)
LS Mean Change from Baseline (SE)	27.44 (1.729)	29.69 (1.747)
95% C.I.	(24.05, 30.84)	(26.25, 33.12)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.24 (2.458)
95% C.I.		(-2.59, 7.07)
p-value		0.362
Corrected Hedge’s g (SE) [1]		0.09 (0.102)
95% C.I.		(-0.11, 0.29)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	196	192
LS Mean (SE)	87.46 (1.510)	89.60 (1.526)
95% C.I.	(84.49, 90.42)	(86.60, 92.60)
LS Mean Change from Baseline (SE)	25.19 (1.510)	27.33 (1.526)
95% C.I.	(22.22, 28.16)	(24.33, 30.33)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.14 (2.150)
95% C.I.		(-2.09, 6.37)
p-value		0.320
Corrected Hedge’s g (SE) [1]		0.10 (0.102)
95% C.I.		(-0.10, 0.30)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: General Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	196	192
LS Mean (SE)	70.56 (1.407)	68.83 (1.418)
95% C.I.	(67.79, 73.33)	(66.04, 71.62)
LS Mean Change from Baseline (SE)	14.12 (1.407)	12.39 (1.418)
95% C.I.	(11.36, 16.89)	(9.60, 15.18)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-1.73 (2.002)
95% C.I.		(-5.67, 2.20)
p-value		0.388
Corrected Hedge’s g (SE) [1]		-0.09 (0.102)
95% C.I.		(-0.29, 0.11)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Vitality (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	196	192
LS Mean (SE)	60.78 (2.204)	64.93 (2.225)
95% C.I.	(56.45, 65.12)	(60.56, 69.31)
LS Mean Change from Baseline (SE)	24.64 (2.204)	28.79 (2.225)
95% C.I.	(20.31, 28.97)	(24.42, 33.16)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.15 (3.133)
95% C.I.		(-2.01, 10.31)
p-value		0.186
Corrected Hedge’s g (SE) [1]		0.13 (0.102)
95% C.I.		(-0.06, 0.33)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	196	192
LS Mean (SE)	82.19 (1.848)	86.21 (1.870)
95% C.I.	(78.55, 85.82)	(82.54, 89.89)
LS Mean Change from Baseline (SE)	34.84 (1.848)	38.87 (1.870)
95% C.I.	(31.21, 38.47)	(35.19, 42.54)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.03 (2.628)
95% C.I.		(-1.14, 9.20)
p-value		0.126
Corrected Hedge’s g (SE) [1]		0.16 (0.102)
95% C.I.		(-0.04, 0.35)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	196	192
LS Mean (SE)	85.15 (1.558)	87.84 (1.574)
95% C.I.	(82.08, 88.21)	(84.75, 90.94)
LS Mean Change from Baseline (SE)	18.49 (1.558)	21.19 (1.574)
95% C.I.	(15.43, 21.55)	(18.09, 24.28)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.70 (2.214)
95% C.I.		(-1.66, 7.05)
p-value		0.224
Corrected Hedge’s g (SE) [1]		0.12 (0.102)
95% C.I.		(-0.08, 0.32)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Mental Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	196	192
LS Mean (SE)	74.93 (1.511)	78.83 (1.527)
95% C.I.	(71.96, 77.90)	(75.83, 81.83)
LS Mean Change from Baseline (SE)	16.35 (1.511)	20.25 (1.527)
95% C.I.	(13.38, 19.32)	(17.25, 23.25)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.91 (2.149)
95% C.I.		(-0.32, 8.13)
p-value		0.070
Corrected Hedge’s g (SE) [1]		0.18 (0.102)
95% C.I.		(-0.02, 0.38)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Physical Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	196	192
LS Mean (SE)	51.48 (0.502)	51.44 (0.506)
95% C.I.	(50.50, 52.47)	(50.45, 52.43)
LS Mean Change from Baseline (SE)	7.47 (0.502)	7.43 (0.506)
95% C.I.	(6.49, 8.46)	(6.44, 8.43)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.04 (0.713)
95% C.I.		(-1.44, 1.36)
p-value		0.955
Corrected Hedge’s g (SE) [1]		-0.01 (0.102)
95% C.I.		(-0.20, 0.19)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Mental Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	196	192
LS Mean (SE)	51.62 (0.653)	53.62 (0.660)
95% C.I.	(50.34, 52.90)	(52.32, 54.91)
LS Mean Change from Baseline (SE)	8.85 (0.653)	10.84 (0.660)
95% C.I.	(7.56, 10.13)	(9.55, 12.14)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.00 (0.928)
95% C.I.		(0.17, 3.82)
p-value		0.032
Corrected Hedge’s g (SE) [1]		0.22 (0.102)
95% C.I.		(0.02, 0.42)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Health Utility Index

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	196	192
LS Mean (SE)	0.80 (0.010)	0.84 (0.010)
95% C.I.	(0.78, 0.82)	(0.82, 0.86)
LS Mean Change from Baseline (SE)	0.16 (0.010)	0.19 (0.010)
95% C.I.	(0.14, 0.18)	(0.17, 0.21)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.03 (0.015)
95% C.I.		(0.01, 0.06)
p-value		0.022
Corrected Hedge’s g (SE) [1]		0.23 (0.102)
95% C.I.		(0.03, 0.43)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	196	192
LS Mean (SE)	79.92 (1.608)	82.88 (1.625)
95% C.I.	(76.76, 83.08)	(79.69, 86.08)
LS Mean Change from Baseline (SE)	30.92 (1.608)	33.89 (1.625)
95% C.I.	(27.76, 34.09)	(30.69, 37.08)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.96 (2.287)
95% C.I.		(-1.53, 7.46)
p-value		0.196
Corrected Hedge’s g (SE) [1]		0.13 (0.102)
95% C.I.		(-0.07, 0.33)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	196	192
LS Mean (SE)	68.32 (1.672)	71.81 (1.689)
95% C.I.	(65.04, 71.61)	(68.49, 75.13)
LS Mean Change from Baseline (SE)	28.36 (1.672)	31.85 (1.689)
95% C.I.	(25.08, 31.65)	(28.53, 35.17)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.48 (2.377)
95% C.I.		(-1.19, 8.16)
p-value		0.144
Corrected Hedge’s g (SE) [1]		0.15 (0.102)
95% C.I.		(-0.05, 0.35)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	56	56
n	19	17
LS Mean (SE)	71.96 (6.151)	69.69 (6.521)
95% C.I.	(59.87, 84.05)	(56.87, 82.51)
LS Mean Change from Baseline (SE)	12.85 (6.151)	10.58 (6.521)
95% C.I.	(0.76, 24.94)	(-2.24, 23.40)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.27 (8.933)
95% C.I.		(-19.83, 15.29)
p-value		0.799
Corrected Hedge’s g (SE) [1]		-0.08 (0.334)
95% C.I.		(-0.74, 0.57)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Role Physical (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	19	17
LS Mean (SE)	70.43 (5.558)	69.46 (5.872)
95% C.I.	(59.50, 81.36)	(57.92, 81.00)
LS Mean Change from Baseline (SE)	19.10 (5.558)	18.13 (5.872)
95% C.I.	(8.18, 30.03)	(6.59, 29.67)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.97 (8.084)
95% C.I.		(-16.86, 14.92)
p-value		0.904
Corrected Hedge’s g (SE) [1]		-0.04 (0.334)
95% C.I.		(-0.69, 0.62)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	19	17
LS Mean (SE)	77.60 (4.849)	79.82 (5.138)
95% C.I.	(68.06, 87.13)	(69.72, 89.92)
LS Mean Change from Baseline (SE)	15.33 (4.849)	17.55 (5.138)
95% C.I.	(5.80, 24.86)	(7.45, 27.65)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.22 (7.077)
95% C.I.		(-11.69, 16.13)
p-value		0.754
Corrected Hedge’s g (SE) [1]		0.10 (0.334)
95% C.I.		(-0.55, 0.76)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: General Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	19	17
LS Mean (SE)	75.06 (4.533)	64.90 (4.763)
95% C.I.	(66.15, 83.97)	(55.54, 74.26)
LS Mean Change from Baseline (SE)	18.62 (4.533)	8.46 (4.763)
95% C.I.	(9.71, 27.53)	(-0.90, 17.83)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-10.16 (6.565)
95% C.I.		(-23.06, 2.75)
p-value		0.123
Corrected Hedge’s g (SE) [1]		-0.50 (0.339)
95% C.I.		(-1.17, 0.16)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Vitality (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	19	17
LS Mean (SE)	59.22 (7.081)	71.71 (7.480)
95% C.I.	(45.30, 73.14)	(57.01, 86.42)
LS Mean Change from Baseline (SE)	23.07 (7.081)	35.57 (7.480)
95% C.I.	(9.15, 36.99)	(20.87, 50.27)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		12.50 (10.290)
95% C.I.		(-7.73, 32.72)
p-value		0.225
Corrected Hedge’s g (SE) [1]		0.40 (0.337)
95% C.I.		(-0.26, 1.06)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	19	17
LS Mean (SE)	69.45 (5.947)	84.94 (6.323)
95% C.I.	(57.76, 81.14)	(72.51, 97.36)
LS Mean Change from Baseline (SE)	22.11 (5.947)	37.59 (6.323)
95% C.I.	(10.42, 33.80)	(25.16, 50.02)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		15.48 (8.647)
95% C.I.		(-1.51, 32.48)
p-value		0.074
Corrected Hedge’s g (SE) [1]		0.58 (0.341)
95% C.I.		(-0.09, 1.25)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	19	17
LS Mean (SE)	79.30 (5.004)	87.60 (5.289)
95% C.I.	(69.46, 89.14)	(77.20, 98.00)
LS Mean Change from Baseline (SE)	12.64 (5.004)	20.94 (5.289)
95% C.I.	(2.81, 22.48)	(10.55, 31.34)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		8.30 (7.280)
95% C.I.		(-6.01, 22.61)
p-value		0.255
Corrected Hedge’s g (SE) [1]		0.37 (0.337)
95% C.I.		(-0.29, 1.03)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Mental Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	19	17
LS Mean (SE)	76.02 (4.854)	83.66 (5.148)
95% C.I.	(66.48, 85.56)	(73.54, 93.78)
LS Mean Change from Baseline (SE)	17.44 (4.854)	25.08 (5.148)
95% C.I.	(7.90, 26.98)	(14.96, 35.20)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		7.64 (7.081)
95% C.I.		(-6.28, 21.56)
p-value		0.281
Corrected Hedge’s g (SE) [1]		0.35 (0.336)
95% C.I.		(-0.31, 1.01)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Physical Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	19	17
LS Mean (SE)	49.39 (1.615)	46.81 (1.701)
95% C.I.	(46.22, 52.57)	(43.47, 50.16)
LS Mean Change from Baseline (SE)	5.39 (1.615)	2.81 (1.701)
95% C.I.	(2.21, 8.56)	(-0.54, 6.15)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.58 (2.339)
95% C.I.		(-7.18, 2.02)
p-value		0.271
Corrected Hedge’s g (SE) [1]		-0.36 (0.337)
95% C.I.		(-1.02, 0.30)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Mental Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	19	17
LS Mean (SE)	50.82 (2.102)	56.57 (2.233)
95% C.I.	(46.69, 54.95)	(52.18, 60.96)
LS Mean Change from Baseline (SE)	8.05 (2.102)	13.80 (2.233)
95% C.I.	(3.92, 12.18)	(9.41, 18.19)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		5.75 (3.054)
95% C.I.		(-0.25, 11.76)
p-value		0.060
Corrected Hedge’s g (SE) [1]		0.61 (0.342)
95% C.I.		(-0.06, 1.28)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Health Utility Index

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	19	17
LS Mean (SE)	0.74 (0.033)	0.81 (0.035)
95% C.I.	(0.67, 0.80)	(0.74, 0.88)
LS Mean Change from Baseline (SE)	0.09 (0.033)	0.16 (0.035)
95% C.I.	(0.03, 0.16)	(0.09, 0.23)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.07 (0.049)
95% C.I.		(-0.03, 0.16)
p-value		0.163
Corrected Hedge’s g (SE) [1]		0.46 (0.338)
95% C.I.		(-0.21, 1.12)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	19	17
LS Mean (SE)	69.52 (5.165)	73.94 (5.462)
95% C.I.	(59.37, 79.67)	(63.20, 84.68)
LS Mean Change from Baseline (SE)	20.52 (5.165)	24.94 (5.462)
95% C.I.	(10.37, 30.67)	(14.21, 35.68)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.42 (7.519)
95% C.I.		(-10.36, 19.20)
p-value		0.557
Corrected Hedge’s g (SE) [1]		0.19 (0.335)
95% C.I.		(-0.46, 0.85)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.23
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	19	17
LS Mean (SE)	61.74 (5.376)	76.02 (5.684)
95% C.I.	(51.17, 72.30)	(64.84, 87.19)
LS Mean Change from Baseline (SE)	21.77 (5.376)	36.05 (5.684)
95% C.I.	(11.21, 32.34)	(24.88, 47.23)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		14.28 (7.814)
95% C.I.		(-1.08, 29.64)
p-value		0.068
Corrected Hedge’s g (SE) [1]		0.60 (0.341)
95% C.I.		(-0.07, 1.26)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.24
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Age Group (<=70, >70) - GBA Approach

Age group (years): <=70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	473	472
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	86 (18%)	104 (22%)
Non-responder	110 (23%)	88 (19%)
Missing [1]	277 (59%)	280 (59%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.79
95% C.I.		(0.57, 1.08)
p-value		0.141
Inverse Relative Risk [3]		0.83
95% C.I.		(0.64, 1.07)
p-value		0.141
Risk Difference (%) [4]		-3.85
95% C.I.		(-8.96, 1.25)
p-value		0.145

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, age (<=70, >70 years old) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

PPD

Table 24.24
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Age Group (<=70, >70) - GBA Approach

Age group (years): >70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	56	56
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	6 (11%)	8 (14%)
Non-responder	13 (23%)	9 (16%)
Missing [1]	37 (66%)	39 (70%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.72
95% C.I.		(0.23, 2.23)
p-value		0.569
Inverse Relative Risk [3]		0.75
95% C.I.		(0.28, 2.02)
p-value		0.570
Risk Difference (%) [4]		-3.57
95% C.I.		(-15.80, 8.66)
p-value		0.777

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, age (<=70, >70 years old) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

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Table 24.25
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Age Group (<=70, >70) - GBA Approach

Age group (years): <=70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	473	472
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	75 (16%)	90 (19%)
Non-responder	121 (26%)	102 (22%)
Missing [1]	277 (59%)	280 (59%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.80
95% C.I.		(0.57, 1.12)
p-value		0.195
Inverse Relative Risk [3]		0.83
95% C.I.		(0.63, 1.10)
p-value		0.195
Risk Difference (%) [4]		-3.21
95% C.I.		(-8.05, 1.63)
p-value		0.200

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, age (<=70, >70 years old) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

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Table 24.25
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Age Group (<=70, >70) - GBA Approach

Age group (years): >70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	56	56
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	8 (14%)	6 (11%)
Non-responder	11 (20%)	11 (20%)
Missing [1]	37 (66%)	39 (70%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.39
95% C.I.		(0.45, 4.30)
p-value		0.569
Inverse Relative Risk [3]		1.33
95% C.I.		(0.49, 3.59)
p-value		0.570
Risk Difference (%) [4]		3.57
95% C.I.		(-8.66, 15.80)
p-value		0.777

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, age (<=70, >70 years old) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

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Table 24.26
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Age Group (<=70, >70) - QualityMetric Approach

Age group (years): <=70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	473	472
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	106 (22%)	118 (25%)
Non-responder	90 (19%)	74 (16%)
Missing [1]	277 (59%)	280 (59%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.87
95% C.I.		(0.64, 1.17)
p-value		0.350
Inverse Relative Risk [3]		0.90
95% C.I.		(0.71, 1.13)
p-value		0.350
Risk Difference (%) [4]		-2.59
95% C.I.		(-8.01, 2.83)
p-value		0.360

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, age (<=70, >70 years old) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

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Table 24.26
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Age Group (<=70, >70) - QualityMetric Approach

Age group (years): >70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	56	56
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	7 (13%)	9 (16%)
Non-responder	12 (21%)	8 (14%)
Missing [1]	37 (66%)	39 (70%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.75
95% C.I.		(0.26, 2.17)
p-value		0.590
Inverse Relative Risk [3]		0.78
95% C.I.		(0.31, 1.94)
p-value		0.591
Risk Difference (%) [4]		-3.57
95% C.I.		(-16.52, 9.37)
p-value		0.788

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, age (<=70, >70 years old) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

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Population: Intent-to-Treat Data as of 27APR2021

Table 24.27
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Age Group (<=70, >70) - QualityMetric Approach

Age group (years): <=70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	473	472
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	94 (20%)	108 (23%)
Non-responder	102 (22%)	84 (18%)
Missing [1]	277 (59%)	280 (59%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.84
95% C.I.		(0.61, 1.14)
p-value		0.260
Inverse Relative Risk [3]		0.87
95% C.I.		(0.68, 1.11)
p-value		0.261
Risk Difference (%) [4]		-3.01
95% C.I.		(-8.23, 2.22)
p-value		0.268

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, age (<=70, >70 years old) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Table 24.27
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Age Group (<=70, >70) - QualityMetric Approach

Age group (years): >70
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	56	56
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	10 (18%)	7 (13%)
Non-responder	9 (16%)	10 (18%)
Missing [1]	37 (66%)	39 (70%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.52
95% C.I.		(0.53, 4.33)
p-value		0.432
Inverse Relative Risk [3]		1.43
95% C.I.		(0.59, 3.49)
p-value		0.434
Risk Difference (%) [4]		5.36
95% C.I.		(-7.90, 18.61)
p-value		0.600

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, age (<=70, >70 years old) and age by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		96	98
Baseline	SF-12 Score	n	66	67
		Mean	50.62	53.73
		SD	34.621	34.884
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	32	39
		Mean	82.03	80.13
		SD	27.849	30.981
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	26	30
		Mean	34.96	25.00
		SD	33.647	38.282
		Median	50.00	25.00
		Min.	-25.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	41.52	42.49
		SD	10.899	10.982
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	32	39
		Mean	51.40	50.80
		SD	8.767	9.753
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	26	30
		Mean	11.01	7.87
		SD	10.592	12.051
		Median	15.74	7.87
		Min.	-7.9	-23.6
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	45.27	54.29
		SD	27.541	31.724
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	32	39
		Mean	72.27	82.69
		SD	26.514	23.581
		Median	75.00	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	26	30
		Mean	27.88	27.92
		SD	29.855	32.939
		Median	25.00	31.25
		Min.	-25.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	38.93	41.99
		SD	9.324	10.739
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	32	39
		Mean	48.07	51.60
		SD	8.974	7.981
		Median	49.00	57.46
		Min.	23.6	32.1
		Max.	57.5	57.5
	Change from Baseline	n	26	30
		Mean	9.44	9.45
		SD	10.106	11.150
		Median	8.47	10.58
		Min.	-8.5	-16.9
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	65	67
		Mean	60.77	57.09
		SD	24.988	32.800
		Median	50.00	50.00
		Min.	25.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	32	39
		Mean	82.03	80.13
		SD	23.958	29.901
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	26	30
		Mean	26.92	22.50
		SD	29.089	37.342
		Median	25.00	25.00
		Min.	-50.0	-75.0
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	65	67
		Mean	43.58	42.25
		SD	9.016	11.833
		Median	39.69	39.69
		Min.	30.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	32	39
		Mean	51.25	50.56
		SD	8.643	10.787
		Median	57.73	57.73
		Min.	21.7	21.7
		Max.	57.7	57.7
	Change from Baseline	n	26	30
		Mean	9.71	8.12
		SD	10.494	13.473
		Median	9.02	9.02
		Min.	-18.0	-27.1
		Max.	27.1	27.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	58.64	55.37
		SD	28.427	31.722
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	32	39
		Mean	67.50	67.95
		SD	22.216	21.876
		Median	60.00	60.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	26	30
		Mean	10.38	21.33
		SD	22.624	34.961
		Median	0.00	12.50
		Min.	-40.0	-60.0
		Max.	60.0	85.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	47.21	45.91
		SD	11.301	12.611
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	32	39
		Mean	50.73	50.91
		SD	8.833	8.697
		Median	47.75	47.75
		Min.	23.9	33.8
		Max.	63.7	63.7
	Change from Baseline	n	26	30
		Mean	4.13	8.48
		SD	8.995	13.898
		Median	0.00	4.97
		Min.	-15.9	-23.8
		Max.	23.9	33.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	44.70	40.67
		SD	26.860	30.413
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	32	39
		Mean	65.63	65.38
		SD	29.614	35.176
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	26	30
		Mean	26.92	16.67
		SD	27.316	44.689
		Median	25.00	25.00
		Min.	-50.0	-100.0
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	46.98	45.40
		SD	10.569	11.967
		Median	49.07	49.07
		Min.	29.4	29.4
		Max.	68.7	68.7
Day 29	SF-12 Score	n	32	39
		Mean	55.21	55.12
		SD	11.652	13.841
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	26	30
		Mean	10.59	6.56
		SD	10.748	17.584
		Median	9.84	9.83
		Min.	-19.7	-39.3
		Max.	29.5	29.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	50.00	48.88
		SD	34.807	36.782
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	32	39
		Mean	81.25	83.33
		SD	22.895	27.705
		Median	100.00	100.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	26	30
		Mean	41.35	32.50
		SD	35.315	38.366
		Median	50.00	50.00
		Min.	-25.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	39.11	38.71
		SD	12.384	13.087
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	32	39
		Mean	50.23	50.97
		SD	8.145	9.856
		Median	56.90	56.90
		Min.	30.2	21.3
		Max.	56.9	56.9
	Change from Baseline	n	26	30
		Mean	14.71	11.56
		SD	12.564	13.650
		Median	17.79	17.79
		Min.	-8.9	-26.7
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	58.33	61.57
		SD	28.532	31.027
		Median	50.00	62.50
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	32	39
		Mean	80.08	85.58
		SD	26.727	22.127
		Median	100.00	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	26	30
		Mean	24.52	22.08
		SD	31.520	28.558
		Median	25.00	18.75
		Min.	-50.0	-25.0
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	38.95	40.30
		SD	11.865	12.902
		Median	35.49	40.69
		Min.	14.7	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	32	39
		Mean	48.00	50.28
		SD	11.113	9.201
		Median	56.28	56.28
		Min.	14.7	25.1
		Max.	56.3	56.3
	Change from Baseline	n	26	30
		Mean	10.20	9.18
		SD	13.107	11.875
		Median	10.40	7.79
		Min.	-20.8	-10.4
		Max.	31.2	31.2

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	58.33	54.66
		SD	21.963	25.454
		Median	50.00	50.00
		Min.	12.5	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	32	39
		Mean	74.61	75.00
		SD	22.781	23.993
		Median	75.00	75.00
		Min.	12.5	25.0
		Max.	100.0	100.0
	Change from Baseline	n	26	30
		Mean	22.60	22.08
		SD	29.584	31.942
		Median	12.50	25.00
		Min.	-25.0	-50.0
		Max.	75.0	87.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	45.09	43.40
		SD	10.080	11.680
		Median	41.26	41.26
		Min.	24.1	18.3
		Max.	64.2	64.2
Day 29	SF-12 Score	n	32	39
		Mean	52.56	52.74
		SD	10.455	11.011
		Median	52.74	52.74
		Min.	24.1	29.8
		Max.	64.2	64.2
	Change from Baseline	n	26	30
		Mean	10.37	10.14
		SD	13.579	14.659
		Median	5.74	11.48
		Min.	-11.5	-23.0
		Max.	34.4	40.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	43.05	43.79
		SD	8.554	9.210
		Median	43.47	43.67
		Min.	25.5	23.0
		Max.	58.9	62.7
Day 29	SF-12 Score	n	32	39
		Mean	50.47	50.79
		SD	8.424	9.158
		Median	51.72	53.65
		Min.	27.1	29.8
		Max.	65.3	69.4
	Change from Baseline	n	26	30
		Mean	8.04	7.45
		SD	8.695	10.706
		Median	8.10	6.84
		Min.	-6.7	-13.6
		Max.	31.0	27.2

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	43.15	42.00
		SD	9.647	11.252
		Median	40.95	40.51
		Min.	19.3	16.3
		Max.	63.9	64.3
Day 29	SF-12 Score	n	32	39
		Mean	51.44	52.47
		SD	9.855	9.613
		Median	52.52	51.49
		Min.	28.7	20.4
		Max.	64.7	64.8
	Change from Baseline	n	26	30
		Mean	11.21	9.66
		SD	11.343	13.215
		Median	10.88	9.75
		Min.	-8.8	-16.6
		Max.	30.1	41.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	65	67
		Mean	0.644	0.646
		SD	0.1187	0.1701
		Median	0.630	0.615
		Min.	0.43	0.35
		Max.	1.00	1.00
Day 29	SF-12 Score	n	32	39
		Mean	0.794	0.818
		SD	0.1525	0.1784
		Median	0.807	0.859
		Min.	0.42	0.43
		Max.	1.00	1.00
	Change from Baseline	n	26	30
		Mean	0.178	0.146
		SD	0.1653	0.1958
		Median	0.188	0.115
		Min.	-0.09	-0.29
		Max.	0.48	0.48

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	45.55	50.65
		SD	25.892	31.610
		Median	46.88	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	32	39
		Mean	74.41	83.97
		SD	23.079	23.769
		Median	81.25	100.00
		Min.	25.0	18.8
		Max.	100.0	100.0
	Change from Baseline	n	26	30
		Mean	29.33	32.50
		SD	29.621	30.504
		Median	28.13	31.25
		Min.	-12.5	-18.8
		Max.	93.8	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	37.59	39.43
		SD	9.303	11.358
		Median	38.07	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 29	SF-12 Score	n	32	39
		Mean	47.96	51.40
		SD	8.293	8.542
		Median	50.42	57.16
		Min.	30.2	28.0
		Max.	57.2	57.2
	Change from Baseline	n	26	30
		Mean	10.54	11.68
		SD	10.644	10.961
		Median	10.11	11.23
		Min.	-4.5	-6.7
		Max.	33.7	35.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	46.40	41.51
		SD	22.841	28.386
		Median	50.00	43.75
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	32	39
		Mean	69.73	72.76
		SD	23.229	28.623
		Median	68.75	81.25
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	26	30
		Mean	28.61	26.88
		SD	25.383	30.888
		Median	28.13	31.25
		Min.	0.0	-50.0
		Max.	81.3	87.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	66	67
		Mean	44.95	42.62
		SD	10.857	13.493
		Median	46.66	43.69
		Min.	22.9	22.9
		Max.	70.4	70.4
Day 29	SF-12 Score	n	32	39
		Mean	56.03	57.47
		SD	11.039	13.603
		Median	55.57	61.51
		Min.	34.8	22.9
		Max.	70.4	70.4
	Change from Baseline	n	26	30
		Mean	13.60	12.77
		SD	12.064	14.681
		Median	13.37	14.85
		Min.	0.0	-23.8
		Max.	38.6	41.6

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		84	72
Baseline	SF-12 Score	n	61	59
		Mean	50.26	57.20
		SD	32.225	32.843
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	44	33
		Mean	77.84	81.82
		SD	27.606	31.420
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	37	29
		Mean	26.35	38.79
		SD	35.817	40.963
		Median	25.00	50.00
		Min.	-50.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	61	59
		Mean	41.40	43.59
		SD	10.144	10.339
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	44	33
		Mean	50.08	51.34
		SD	8.690	9.891
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	37	29
		Mean	8.30	12.21
		SD	11.275	12.895
		Median	7.87	15.74
		Min.	-15.7	-31.5
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	46.25	45.55
		SD	24.819	25.927
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	44	33
		Mean	75.85	76.89
		SD	21.967	31.269
		Median	75.00	100.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	37	29
		Mean	25.00	40.09
		SD	26.352	37.705
		Median	25.00	50.00
		Min.	-12.5	-62.5
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	39.27	39.03
		SD	8.403	8.777
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	44	33
		Mean	49.29	49.64
		SD	7.435	10.585
		Median	49.00	57.46
		Min.	32.1	23.6
		Max.	57.5	57.5
	Change from Baseline	n	37	29
		Mean	8.46	13.57
		SD	8.920	12.763
		Median	8.46	16.92
		Min.	-4.2	-21.2
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	55.42	57.63
		SD	27.652	30.883
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	44	33
		Mean	81.25	93.18
		SD	24.187	16.855
		Median	100.00	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	37	29
		Mean	21.62	42.24
		SD	25.794	29.958
		Median	25.00	50.00
		Min.	-25.0	-25.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	41.65	42.44
		SD	9.976	11.140
		Median	39.69	39.69
		Min.	21.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	44	33
		Mean	50.97	55.27
		SD	8.726	6.081
		Median	57.73	57.73
		Min.	21.7	30.7
		Max.	57.7	57.7
	Change from Baseline	n	37	29
		Mean	7.80	15.24
		SD	9.307	10.807
		Median	9.02	18.04
		Min.	-9.0	-9.0
		Max.	27.1	36.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	61	59
		Mean	50.90	51.44
		SD	29.404	30.044
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	44	33
		Mean	69.32	67.73
		SD	18.571	21.363
		Median	60.00	60.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	37	29
		Mean	15.14	15.69
		SD	20.052	39.341
		Median	0.00	0.00
		Min.	0.0	-100.0
		Max.	75.0	85.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	61	59
		Mean	44.14	44.35
		SD	11.689	11.944
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	44	33
		Mean	51.46	50.82
		SD	7.385	8.495
		Median	47.75	47.75
		Min.	33.8	23.9
		Max.	63.7	63.7
	Change from Baseline	n	37	29
		Mean	6.02	6.24
		SD	7.971	15.640
		Median	0.00	0.00
		Min.	0.0	-39.8
		Max.	29.8	33.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	40.42	38.98
		SD	28.779	29.460
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	44	32
		Mean	71.59	79.69
		SD	25.626	32.650
		Median	75.00	100.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	37	29
		Mean	25.68	40.52
		SD	32.535	41.947
		Median	25.00	50.00
		Min.	-25.0	-100.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	45.30	44.73
		SD	11.324	11.593
		Median	49.07	49.07
		Min.	29.4	29.4
		Max.	68.7	68.7
Day 29	SF-12 Score	n	44	32
		Mean	57.56	60.75
		SD	10.082	12.847
		Median	58.90	68.74
		Min.	39.2	29.4
		Max.	68.7	68.7
	Change from Baseline	n	37	29
		Mean	10.10	15.94
		SD	12.801	16.505
		Median	9.83	19.67
		Min.	-9.8	-39.3
		Max.	29.5	39.3

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	42.50	41.10
		SD	29.936	32.418
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	44	33
		Mean	77.27	83.33
		SD	25.184	29.092
		Median	75.00	100.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	37	29
		Mean	29.05	45.69
		SD	30.908	42.819
		Median	25.00	50.00
		Min.	-25.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	36.44	35.95
		SD	10.651	11.535
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	44	33
		Mean	48.82	50.97
		SD	8.959	10.350
		Median	48.01	56.90
		Min.	30.2	21.3
		Max.	56.9	56.9
	Change from Baseline	n	37	29
		Mean	10.34	16.26
		SD	10.997	15.235
		Median	8.90	17.79
		Min.	-8.9	-26.7
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	57.71	58.05
		SD	27.337	28.120
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	44	33
		Mean	80.40	80.68
		SD	21.967	30.950
		Median	93.75	100.00
		Min.	37.5	0.0
		Max.	100.0	100.0
	Change from Baseline	n	37	29
		Mean	18.92	33.19
		SD	23.867	39.988
		Median	0.00	50.00
		Min.	-12.5	-62.5
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	38.70	38.84
		SD	11.368	11.693
		Median	35.49	35.49
		Min.	14.7	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	44	33
		Mean	48.13	48.25
		SD	9.134	12.870
		Median	53.68	56.28
		Min.	30.3	14.7
		Max.	56.3	56.3
	Change from Baseline	n	37	29
		Mean	7.87	13.80
		SD	9.925	16.627
		Median	0.00	20.79
		Min.	-5.2	-26.0
		Max.	31.2	41.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	51.25	53.18
		SD	23.209	20.048
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	44	33
		Mean	80.11	77.27
		SD	19.868	24.498
		Median	87.50	87.50
		Min.	37.5	12.5
		Max.	100.0	100.0
	Change from Baseline	n	37	29
		Mean	24.32	29.74
		SD	24.641	31.941
		Median	25.00	37.50
		Min.	-37.5	-25.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	41.84	42.72
		SD	10.650	9.201
		Median	41.26	41.26
		Min.	18.3	18.3
		Max.	64.2	64.2
Day 29	SF-12 Score	n	44	33
		Mean	55.08	53.78
		SD	9.119	11.243
		Median	58.47	58.47
		Min.	35.5	24.1
		Max.	64.2	64.2
	Change from Baseline	n	37	29
		Mean	11.16	13.65
		SD	11.309	14.659
		Median	11.47	17.21
		Min.	-17.2	-11.5
		Max.	34.4	45.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	42.26	43.32
		SD	8.707	8.841
		Median	41.74	43.93
		Min.	21.5	22.4
		Max.	60.5	61.0
Day 29	SF-12 Score	n	44	33
		Mean	49.92	52.10
		SD	6.722	6.864
		Median	50.82	53.65
		Min.	25.0	23.6
		Max.	59.0	60.2
	Change from Baseline	n	37	29
		Mean	6.71	11.01
		SD	7.845	9.387
		Median	5.82	11.57
		Min.	-9.2	-19.7
		Max.	26.0	28.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	40.64	40.25
		SD	10.767	9.633
		Median	40.51	40.51
		Min.	14.3	11.0
		Max.	73.0	62.4
Day 29	SF-12 Score	n	44	33
		Mean	53.07	52.92
		SD	9.750	10.605
		Median	54.98	56.77
		Min.	34.0	29.8
		Max.	65.6	64.7
	Change from Baseline	n	37	29
		Mean	10.19	14.68
		SD	11.604	14.416
		Median	7.18	18.85
		Min.	-12.9	-16.0
		Max.	33.5	43.7

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	0.613	0.616
		SD	0.1265	0.1158
		Median	0.615	0.615
		Min.	0.35	0.35
		Max.	1.00	1.00
Day 29	SF-12 Score	n	44	32
		Mean	0.785	0.852
		SD	0.1601	0.1653
		Median	0.766	0.922
		Min.	0.52	0.48
		Max.	1.00	1.00
	Change from Baseline	n	37	29
		Mean	0.147	0.271
		SD	0.1573	0.2125
		Median	0.105	0.338
		Min.	-0.14	-0.31
		Max.	0.39	0.66

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	44.69	44.07
		SD	24.133	25.571
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	44	33
		Mean	76.99	79.73
		SD	19.004	29.648
		Median	75.00	100.00
		Min.	37.5	6.3
		Max.	100.0	100.0
	Change from Baseline	n	37	29
		Mean	26.69	43.97
		SD	23.600	36.232
		Median	25.00	50.00
		Min.	-25.0	-56.3
		Max.	87.5	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	37.28	37.06
		SD	8.670	9.187
		Median	39.19	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 29	SF-12 Score	n	44	33
		Mean	48.89	49.88
		SD	6.829	10.653
		Median	48.17	57.16
		Min.	34.7	23.5
		Max.	57.2	57.2
	Change from Baseline	n	37	29
		Mean	9.59	15.80
		SD	8.480	13.018
		Median	8.98	17.97
		Min.	-9.0	-20.2
		Max.	31.4	35.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	42.50	41.21
		SD	22.514	25.563
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	93.8	100.0
Day 29	SF-12 Score	n	44	33
		Mean	75.85	79.42
		SD	21.295	26.175
		Median	81.25	93.75
		Min.	37.5	12.5
		Max.	100.0	100.0
	Change from Baseline	n	37	29
		Mean	28.89	39.44
		SD	26.653	32.652
		Median	25.00	50.00
		Min.	-31.3	-43.8
		Max.	81.3	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	60	59
		Mean	43.09	42.48
		SD	10.703	12.151
		Median	46.66	46.66
		Min.	22.9	22.9
		Max.	67.5	70.4
Day 29	SF-12 Score	n	44	33
		Mean	58.95	60.64
		SD	10.119	12.440
		Median	61.51	67.45
		Min.	40.7	28.8
		Max.	70.4	70.4
	Change from Baseline	n	37	29
		Mean	13.73	18.74
		SD	12.668	15.518
		Median	11.88	23.76
		Min.	-14.9	-20.8
		Max.	38.6	47.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		58	64
Baseline	SF-12 Score	n	47	49
		Mean	60.11	56.63
		SD	31.562	27.374
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	36	27
		Mean	83.33	87.04
		SD	24.640	26.285
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	33	25
		Mean	20.45	35.00
		SD	33.920	31.458
		Median	0.00	50.00
		Min.	-25.0	-25.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	44.50	43.41
		SD	9.936	8.617
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	36	27
		Mean	51.81	52.98
		SD	7.757	8.274
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	33	25
		Mean	6.44	11.02
		SD	10.678	9.903
		Median	0.00	15.74
		Min.	-7.9	-7.9
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	52.39	51.02
		SD	26.017	28.849
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	36	27
		Mean	77.43	83.80
		SD	28.161	23.466
		Median	93.75	87.50
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	33	25
		Mean	26.52	40.50
		SD	36.277	34.851
		Median	25.00	50.00
		Min.	-50.0	-25.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	41.35	40.88
		SD	8.807	9.766
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	36	27
		Mean	49.82	51.98
		SD	9.531	7.942
		Median	55.35	53.23
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	33	25
		Mean	8.97	13.71
		SD	12.280	11.797
		Median	8.46	16.92
		Min.	-16.9	-8.5
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	67.55	61.22
		SD	26.537	27.510
		Median	75.00	75.00
		Min.	25.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	36	27
		Mean	87.50	93.52
		SD	23.528	17.803
		Median	100.00	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	33	25
		Mean	21.97	33.00
		SD	30.464	30.380
		Median	25.00	25.00
		Min.	-50.0	-25.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	46.02	43.74
		SD	9.575	9.925
		Median	48.71	48.71
		Min.	30.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	36	27
		Mean	53.22	55.39
		SD	8.488	6.423
		Median	57.73	57.73
		Min.	21.7	30.7
		Max.	57.7	57.7
	Change from Baseline	n	33	25
		Mean	7.93	11.91
		SD	10.991	10.960
		Median	9.02	9.02
		Min.	-18.0	-9.0
		Max.	27.1	36.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	56.38	50.41
		SD	23.927	29.027
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	36	27
		Mean	72.92	65.56
		SD	17.500	21.409
		Median	60.00	60.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	33	25
		Mean	16.21	14.20
		SD	25.312	32.904
		Median	15.00	0.00
		Min.	-35.0	-60.0
		Max.	85.0	85.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	46.31	43.94
		SD	9.512	11.539
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	36	27
		Mean	52.89	49.96
		SD	6.959	8.512
		Median	47.75	47.75
		Min.	33.8	23.9
		Max.	63.7	63.7
	Change from Baseline	n	33	25
		Mean	6.45	5.65
		SD	10.063	13.081
		Median	5.97	0.00
		Min.	-13.9	-23.9
		Max.	33.8	33.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	37.23	32.65
		SD	25.998	25.106
		Median	50.00	25.00
		Min.	0.0	0.0
		Max.	100.0	75.0
Day 29	SF-12 Score	n	36	27
		Mean	66.67	75.00
		SD	33.806	31.009
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	33	25
		Mean	30.30	44.00
		SD	32.330	32.500
		Median	25.00	50.00
		Min.	-50.0	0.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	44.04	42.24
		SD	10.231	9.880
		Median	49.07	39.23
		Min.	29.4	29.4
		Max.	68.7	58.9
Day 29	SF-12 Score	n	36	27
		Mean	55.62	58.90
		SD	13.302	12.201
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	33	25
		Mean	11.92	17.31
		SD	12.722	12.788
		Median	9.84	19.67
		Min.	-19.7	0.0
		Max.	39.3	39.3

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	51.60	49.49
		SD	33.135	34.038
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	36	27
		Mean	82.64	86.11
		SD	27.915	26.251
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	33	25
		Mean	33.33	34.00
		SD	40.344	38.784
		Median	50.00	25.00
		Min.	-50.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	39.68	38.93
		SD	11.790	12.111
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	36	27
		Mean	50.72	51.96
		SD	9.931	9.339
		Median	56.90	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	33	25
		Mean	11.86	12.10
		SD	14.353	13.799
		Median	17.79	8.90
		Min.	-17.8	-17.8
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	63.83	65.05
		SD	23.201	22.819
		Median	50.00	62.50
		Min.	12.5	12.5
		Max.	100.0	100.0
Day 29	SF-12 Score	n	36	27
		Mean	84.03	91.67
		SD	26.324	20.510
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	33	25
		Mean	23.48	32.00
		SD	30.097	30.636
		Median	25.00	50.00
		Min.	-25.0	-37.5
		Max.	87.5	87.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	41.24	41.75
		SD	9.648	9.489
		Median	35.49	40.69
		Min.	19.9	19.9
		Max.	56.3	56.3
Day 29	SF-12 Score	n	36	27
		Mean	49.64	52.82
		SD	10.946	8.528
		Median	56.28	56.28
		Min.	14.7	14.7
		Max.	56.3	56.3
	Change from Baseline	n	33	25
		Mean	9.77	13.31
		SD	12.515	12.739
		Median	10.40	20.79
		Min.	-10.4	-15.6
		Max.	36.4	36.4

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	58.51	56.89
		SD	17.113	25.777
		Median	50.00	50.00
		Min.	25.0	12.5
		Max.	100.0	100.0
Day 29	SF-12 Score	n	36	27
		Mean	77.08	81.48
		SD	25.266	23.861
		Median	87.50	100.00
		Min.	12.5	25.0
		Max.	100.0	100.0
	Change from Baseline	n	33	25
		Mean	20.83	28.50
		SD	28.755	30.087
		Median	25.00	25.00
		Min.	-25.0	-37.5
		Max.	75.0	87.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	45.17	44.42
		SD	7.854	11.829
		Median	41.26	41.26
		Min.	29.8	24.1
		Max.	64.2	64.2
Day 29	SF-12 Score	n	36	27
		Mean	53.69	55.71
		SD	11.595	10.951
		Median	58.47	64.21
		Min.	24.1	29.8
		Max.	64.2	64.2
	Change from Baseline	n	33	25
		Mean	9.56	13.08
		SD	13.196	13.808
		Median	11.47	11.47
		Min.	-11.5	-17.2
		Max.	34.4	40.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	45.10	43.18
		SD	8.382	9.007
		Median	44.75	43.93
		Min.	18.0	26.6
		Max.	59.4	61.9
Day 29	SF-12 Score	n	36	27
		Mean	51.86	52.10
		SD	6.040	8.108
		Median	53.07	53.65
		Min.	38.6	26.1
		Max.	61.7	59.7
	Change from Baseline	n	33	25
		Mean	6.28	9.64
		SD	7.655	8.968
		Median	4.49	9.35
		Min.	-8.0	-6.0
		Max.	24.9	25.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	42.45	42.25
		SD	8.373	9.607
		Median	42.77	40.51
		Min.	17.2	23.8
		Max.	56.7	65.4
Day 29	SF-12 Score	n	36	27
		Mean	52.40	55.17
		SD	11.809	9.182
		Median	56.57	57.42
		Min.	16.0	29.0
		Max.	64.7	66.8
	Change from Baseline	n	33	25
		Mean	11.42	13.98
		SD	12.671	12.805
		Median	8.77	14.08
		Min.	-8.5	-9.7
		Max.	45.3	38.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	0.647	0.629
		SD	0.1026	0.1042
		Median	0.615	0.615
		Min.	0.47	0.37
		Max.	0.92	0.92
Day 29	SF-12 Score	n	36	27
		Mean	0.823	0.860
		SD	0.1720	0.1498
		Median	0.891	0.922
		Min.	0.41	0.48
		Max.	1.00	1.00
	Change from Baseline	n	33	25
		Mean	0.190	0.257
		SD	0.1867	0.1873
		Median	0.202	0.323
		Min.	-0.13	-0.06
		Max.	0.52	0.63

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	51.99	46.94
		SD	25.105	26.490
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	36	27
		Mean	80.21	85.65
		SD	25.899	22.589
		Median	90.63	93.75
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	33	25
		Mean	31.06	43.25
		SD	31.695	33.019
		Median	37.50	50.00
		Min.	-31.3	-25.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	39.91	38.09
		SD	9.019	9.517
		Median	39.19	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 29	SF-12 Score	n	36	27
		Mean	50.05	52.00
		SD	9.306	8.117
		Median	53.79	54.91
		Min.	21.2	21.2
		Max.	57.2	57.2
	Change from Baseline	n	33	25
		Mean	11.16	15.54
		SD	11.388	11.864
		Median	13.47	17.97
		Min.	-11.2	-9.0
		Max.	35.9	35.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	43.09	40.05
		SD	23.682	22.961
		Median	50.00	43.75
		Min.	0.0	0.0
		Max.	100.0	93.8
Day 29	SF-12 Score	n	36	27
		Mean	72.74	77.78
		SD	26.056	27.861
		Median	75.00	93.75
		Min.	12.5	0.0
		Max.	100.0	100.0
	Change from Baseline	n	33	25
		Mean	30.11	42.50
		SD	27.084	32.073
		Median	31.25	50.00
		Min.	-18.8	-12.5
		Max.	93.8	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	43.37	41.93
		SD	11.258	10.915
		Median	46.66	43.69
		Min.	22.9	22.9
		Max.	70.4	67.5
Day 29	SF-12 Score	n	36	27
		Mean	57.47	59.86
		SD	12.384	13.242
		Median	58.54	67.45
		Min.	28.8	22.9
		Max.	70.4	70.4
	Change from Baseline	n	33	25
		Mean	14.31	20.20
		SD	12.873	15.244
		Median	14.85	23.76
		Min.	-8.9	-5.9
		Max.	44.6	47.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		60	74
Baseline	SF-12 Score	n	43	59
		Mean	55.81	60.17
		SD	33.111	32.203
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	33	39
		Mean	83.33	83.33
		SD	23.105	29.985
		Median	100.00	100.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	24	35
		Mean	28.13	18.57
		SD	33.226	32.845
		Median	25.00	0.00
		Min.	-25.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	43.15	44.52
		SD	10.423	10.138
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	33	39
		Mean	51.81	51.81
		SD	7.274	9.439
		Median	57.06	57.06
		Min.	33.5	25.6
		Max.	57.1	57.1
	Change from Baseline	n	24	35
		Mean	8.85	5.85
		SD	10.459	10.340
		Median	7.87	0.00
		Min.	-7.9	-15.7
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	53.20	54.03
		SD	30.016	28.089
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	33	39
		Mean	78.03	84.29
		SD	21.431	24.622
		Median	75.00	100.00
		Min.	25.0	12.5
		Max.	100.0	100.0
	Change from Baseline	n	24	35
		Mean	32.29	28.57
		SD	28.532	32.309
		Median	25.00	25.00
		Min.	-12.5	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	41.62	41.90
		SD	10.161	9.509
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	33	39
		Mean	50.03	52.14
		SD	7.253	8.334
		Median	49.00	57.46
		Min.	32.1	27.8
		Max.	57.5	57.5
	Change from Baseline	n	24	35
		Mean	10.93	9.67
		SD	9.659	10.937
		Median	8.46	8.46
		Min.	-4.2	-16.9
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	66.86	59.75
		SD	30.726	32.832
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	33	39
		Mean	95.45	90.38
		SD	11.617	20.371
		Median	100.00	100.00
		Min.	50.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	24	35
		Mean	37.50	27.14
		SD	32.134	28.031
		Median	50.00	25.00
		Min.	0.0	-50.0
		Max.	100.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	45.77	43.21
		SD	11.085	11.844
		Median	48.71	48.71
		Min.	21.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	33	39
		Mean	56.09	54.26
		SD	4.191	7.350
		Median	57.73	57.73
		Min.	39.7	30.7
		Max.	57.7	57.7
	Change from Baseline	n	24	35
		Mean	13.53	9.79
		SD	11.593	10.113
		Median	18.04	9.02
		Min.	0.0	-18.0
		Max.	36.1	27.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	58.14	48.14
		SD	28.515	28.222
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	33	39
		Mean	77.73	71.41
		SD	18.670	19.089
		Median	85.00	60.00
		Min.	25.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	24	35
		Mean	17.50	21.00
		SD	27.897	28.123
		Median	0.00	25.00
		Min.	-25.0	-25.0
		Max.	85.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	47.01	43.04
		SD	11.336	11.219
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	33	39
		Mean	54.80	52.29
		SD	7.425	7.591
		Median	57.69	47.75
		Min.	33.8	33.8
		Max.	63.7	63.7
	Change from Baseline	n	24	35
		Mean	6.96	8.35
		SD	11.091	11.181
		Median	0.00	9.94
		Min.	-9.9	-9.9
		Max.	33.8	29.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	34.88	34.75
		SD	26.243	26.268
		Median	25.00	25.00
		Min.	0.0	0.0
		Max.	100.0	75.0
Day 29	SF-12 Score	n	33	39
		Mean	56.82	71.79
		SD	31.420	29.901
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	24	35
		Mean	25.00	35.00
		SD	35.355	33.868
		Median	25.00	25.00
		Min.	-50.0	-50.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	43.12	43.06
		SD	10.327	10.336
		Median	39.23	39.23
		Min.	29.4	29.4
		Max.	68.7	58.9
Day 29	SF-12 Score	n	33	39
		Mean	51.75	57.64
		SD	12.363	11.765
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	24	35
		Mean	9.84	13.77
		SD	13.913	13.327
		Median	9.84	9.84
		Min.	-19.7	-19.7
		Max.	29.5	39.3

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	51.16	44.07
		SD	36.982	38.096
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	33	39
		Mean	85.61	85.90
		SD	21.678	22.794
		Median	100.00	100.00
		Min.	25.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	24	35
		Mean	29.17	46.43
		SD	39.471	39.826
		Median	25.00	50.00
		Min.	-25.0	-25.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	39.52	37.00
		SD	13.158	13.555
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	33	39
		Mean	51.78	51.88
		SD	7.711	8.109
		Median	56.90	56.90
		Min.	30.2	30.2
		Max.	56.9	56.9
	Change from Baseline	n	24	35
		Mean	10.38	16.52
		SD	14.043	14.169
		Median	8.90	17.79
		Min.	-8.9	-8.9
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	73.26	73.09
		SD	28.684	29.980
		Median	87.50	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	33	39
		Mean	90.91	88.46
		SD	12.988	20.356
		Median	100.00	100.00
		Min.	50.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	24	35
		Mean	16.15	16.43
		SD	25.130	34.000
		Median	6.25	0.00
		Min.	-25.0	-50.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	45.16	45.09
		SD	11.928	12.466
		Median	51.08	45.89
		Min.	14.7	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	33	39
		Mean	52.50	51.48
		SD	5.399	8.464
		Median	56.28	56.28
		Min.	35.5	25.1
		Max.	56.3	56.3
	Change from Baseline	n	24	35
		Mean	6.71	6.83
		SD	10.450	14.138
		Median	2.60	0.00
		Min.	-10.4	-20.8
		Max.	31.2	41.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	59.88	61.65
		SD	25.231	25.834
		Median	50.00	62.50
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	33	39
		Mean	75.00	81.41
		SD	21.875	19.210
		Median	75.00	87.50
		Min.	37.5	37.5
		Max.	100.0	100.0
	Change from Baseline	n	24	35
		Mean	16.67	22.14
		SD	27.991	30.481
		Median	12.50	12.50
		Min.	-37.5	-25.0
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	45.80	46.61
		SD	11.579	11.855
		Median	41.26	47.00
		Min.	18.3	18.3
		Max.	64.2	64.2
Day 29	SF-12 Score	n	33	39
		Mean	52.74	55.68
		SD	10.039	8.816
		Median	52.74	58.47
		Min.	35.5	35.5
		Max.	64.2	64.2
	Change from Baseline	n	24	35
		Mean	7.65	10.16
		SD	12.847	13.988
		Median	5.73	5.74
		Min.	-17.2	-11.5
		Max.	34.4	34.4

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	43.80	42.53
		SD	9.476	9.203
		Median	44.57	43.53
		Min.	18.8	20.4
		Max.	60.4	61.6
Day 29	SF-12 Score	n	33	39
		Mean	52.86	52.11
		SD	7.067	7.363
		Median	54.37	53.65
		Min.	35.1	27.7
		Max.	63.4	61.6
	Change from Baseline	n	24	35
		Mean	10.85	7.78
		SD	9.278	8.591
		Median	10.42	6.93
		Min.	-4.9	-15.0
		Max.	35.6	30.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	44.49	44.13
		SD	10.502	11.321
		Median	43.58	44.58
		Min.	17.5	15.8
		Max.	63.3	63.9
Day 29	SF-12 Score	n	33	39
		Mean	52.22	54.58
		SD	7.561	8.065
		Median	51.89	57.28
		Min.	35.4	30.7
		Max.	64.5	62.6
	Change from Baseline	n	24	35
		Mean	6.93	11.96
		SD	10.370	13.030
		Median	5.18	10.97
		Min.	-11.5	-15.3
		Max.	32.7	41.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	0.660	0.645
		SD	0.1228	0.1346
		Median	0.657	0.632
		Min.	0.41	0.35
		Max.	1.00	0.92
Day 29	SF-12 Score	n	33	39
		Mean	0.798	0.843
		SD	0.1071	0.1558
		Median	0.817	0.922
		Min.	0.59	0.51
		Max.	0.94	1.00
	Change from Baseline	n	24	35
		Mean	0.164	0.193
		SD	0.1177	0.1882
		Median	0.147	0.255
		Min.	-0.08	-0.14
		Max.	0.36	0.55

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	51.45	51.38
		SD	29.023	27.589
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	33	39
		Mean	80.87	84.78
		SD	20.309	22.662
		Median	87.50	100.00
		Min.	25.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	24	35
		Mean	33.59	33.04
		SD	28.896	28.983
		Median	28.13	43.75
		Min.	-18.8	-37.5
		Max.	87.5	93.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	39.71	39.69
		SD	10.427	9.912
		Median	39.19	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 29	SF-12 Score	n	33	39
		Mean	50.28	51.69
		SD	7.298	8.144
		Median	52.66	57.16
		Min.	30.2	30.2
		Max.	57.2	57.2
	Change from Baseline	n	24	35
		Mean	12.07	11.87
		SD	10.380	10.413
		Median	10.10	15.72
		Min.	-6.7	-13.5
		Max.	31.4	33.7

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	40.12	41.74
		SD	26.419	22.608
		Median	43.75	43.75
		Min.	0.0	0.0
		Max.	100.0	81.3
Day 29	SF-12 Score	n	33	39
		Mean	68.37	75.48
		SD	21.927	21.382
		Median	75.00	81.25
		Min.	18.8	25.0
		Max.	100.0	100.0
	Change from Baseline	n	24	35
		Mean	34.64	34.82
		SD	23.816	24.029
		Median	34.38	37.50
		Min.	-18.8	-12.5
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	43	59
		Mean	41.96	42.73
		SD	12.559	10.747
		Median	43.69	43.69
		Min.	22.9	22.9
		Max.	70.4	61.5
Day 29	SF-12 Score	n	33	39
		Mean	55.39	58.77
		SD	10.422	10.163
		Median	58.54	61.51
		Min.	31.8	34.8
		Max.	70.4	70.4
	Change from Baseline	n	24	35
		Mean	16.46	16.55
		SD	11.321	11.423
		Median	16.34	17.82
		Min.	-8.9	-5.9
		Max.	35.7	35.7

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		183	159
Baseline	SF-12 Score	n	146	122
		Mean	60.10	57.58
		SD	33.807	35.339
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	89	75
		Mean	75.00	74.00
		SD	27.951	29.763
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	77	67
		Mean	7.79	12.69
		SD	35.877	36.766
		Median	0.00	0.00
		Min.	-75.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	44.50	43.71
		SD	10.642	11.125
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	89	75
		Mean	49.19	48.88
		SD	8.799	9.369
		Median	49.19	49.19
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	77	67
		Mean	2.45	3.99
		SD	11.294	11.574
		Median	0.00	0.00
		Min.	-23.6	-23.6
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	51.28	52.25
		SD	28.456	30.066
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	89	75
		Mean	75.84	74.83
		SD	25.478	27.532
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	77	67
		Mean	25.00	21.08
		SD	31.610	29.852
		Median	25.00	12.50
		Min.	-50.0	-50.0
		Max.	87.5	87.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	40.97	41.30
		SD	9.633	10.178
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	89	75
		Mean	49.28	48.94
		SD	8.624	9.319
		Median	49.00	49.00
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	77	67
		Mean	8.46	7.14
		SD	10.700	10.106
		Median	8.46	4.23
		Min.	-16.9	-16.9
		Max.	29.6	29.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	62.50	64.55
		SD	30.689	28.175
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	89	75
		Mean	85.39	87.00
		SD	21.588	20.697
		Median	100.00	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	77	67
		Mean	21.75	20.90
		SD	29.343	29.707
		Median	25.00	25.00
		Min.	-25.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	44.20	44.94
		SD	11.072	10.165
		Median	48.71	48.71
		Min.	21.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	89	75
		Mean	52.46	53.04
		SD	7.788	7.468
		Median	57.73	57.73
		Min.	21.7	30.7
		Max.	57.7	57.7
	Change from Baseline	n	77	67
		Mean	7.85	7.54
		SD	10.586	10.718
		Median	9.02	9.02
		Min.	-9.0	-18.0
		Max.	36.1	36.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	55.58	58.57
		SD	27.509	27.928
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	89	75
		Mean	69.66	68.33
		SD	22.384	20.107
		Median	60.00	60.00
		Min.	25.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	77	67
		Mean	11.43	6.42
		SD	27.849	26.626
		Median	0.00	0.00
		Min.	-60.0	-40.0
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	46.00	47.18
		SD	10.936	11.102
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	89	75
		Mean	51.59	51.06
		SD	8.899	7.994
		Median	47.75	47.75
		Min.	33.8	33.8
		Max.	63.7	63.7
	Change from Baseline	n	77	67
		Mean	4.54	2.55
		SD	11.071	10.585
		Median	0.00	0.00
		Min.	-23.8	-15.9
		Max.	29.8	29.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	30.31	32.79
		SD	28.041	27.664
		Median	25.00	25.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	89	75
		Mean	48.60	55.33
		SD	31.614	28.562
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	77	67
		Mean	23.05	23.88
		SD	31.353	34.387
		Median	25.00	25.00
		Min.	-50.0	-100.0
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	41.32	42.29
		SD	11.034	10.886
		Median	39.23	39.23
		Min.	29.4	29.4
		Max.	68.7	68.7
Day 29	SF-12 Score	n	89	75
		Mean	48.51	51.17
		SD	12.439	11.238
		Median	49.07	49.07
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	77	67
		Mean	9.07	9.40
		SD	12.337	13.530
		Median	9.84	9.84
		Min.	-19.7	-39.3
		Max.	29.5	29.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	46.23	47.95
		SD	38.990	37.564
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	89	75
		Mean	79.21	85.67
		SD	29.733	25.393
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	77	67
		Mean	32.14	32.84
		SD	44.952	40.172
		Median	25.00	25.00
		Min.	-75.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	37.77	38.38
		SD	13.872	13.365
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	89	75
		Mean	49.51	51.80
		SD	10.578	9.034
		Median	56.90	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	77	67
		Mean	11.44	11.68
		SD	15.993	14.293
		Median	8.90	8.89
		Min.	-26.7	-17.8
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	68.49	70.49
		SD	27.901	30.579
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	89	75
		Mean	83.57	87.50
		SD	23.049	21.845
		Median	100.00	100.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	77	67
		Mean	12.50	12.13
		SD	29.033	26.469
		Median	0.00	0.00
		Min.	-75.0	-50.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	43.18	44.01
		SD	11.603	12.716
		Median	45.89	45.89
		Min.	14.7	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	89	75
		Mean	49.45	51.08
		SD	9.584	9.083
		Median	56.28	56.28
		Min.	25.1	14.7
		Max.	56.3	56.3
	Change from Baseline	n	77	67
		Mean	5.20	5.04
		SD	12.073	11.006
		Median	0.00	0.00
		Min.	-31.2	-20.8
		Max.	31.2	41.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	60.27	62.60
		SD	22.297	22.755
		Median	62.50	62.50
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	89	75
		Mean	70.65	78.00
		SD	21.577	18.816
		Median	75.00	87.50
		Min.	25.0	37.5
		Max.	100.0	100.0
	Change from Baseline	n	77	67
		Mean	9.42	12.69
		SD	21.570	25.975
		Median	12.50	0.00
		Min.	-37.5	-50.0
		Max.	62.5	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	45.98	47.05
		SD	10.232	10.443
		Median	47.00	47.00
		Min.	18.3	18.3
		Max.	64.2	64.2
Day 29	SF-12 Score	n	89	75
		Mean	50.74	54.11
		SD	9.902	8.635
		Median	52.74	58.47
		Min.	29.8	35.5
		Max.	64.2	64.2
	Change from Baseline	n	77	67
		Mean	4.32	5.82
		SD	9.899	11.920
		Median	5.73	0.00
		Min.	-17.2	-23.0
		Max.	28.7	34.4

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	43.70	43.63
		SD	9.429	8.668
		Median	43.90	43.84
		Min.	17.4	20.2
		Max.	62.6	62.1
Day 29	SF-12 Score	n	89	75
		Mean	50.49	49.29
		SD	7.758	8.451
		Median	51.77	50.92
		Min.	22.7	23.5
		Max.	63.8	61.7
	Change from Baseline	n	77	67
		Mean	5.86	5.16
		SD	9.268	8.618
		Median	5.00	3.54
		Min.	-13.3	-11.7
		Max.	31.7	25.7

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	42.76	44.09
		SD	10.152	10.081
		Median	42.80	43.87
		Min.	13.8	14.5
		Max.	70.0	69.3
Day 29	SF-12 Score	n	89	75
		Mean	49.65	53.30
		SD	9.997	8.758
		Median	52.27	55.23
		Min.	18.3	32.4
		Max.	64.6	65.9
	Change from Baseline	n	77	67
		Mean	7.12	7.80
		SD	10.582	10.823
		Median	6.04	6.80
		Min.	-18.4	-20.6
		Max.	37.8	34.3

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	0.648	0.651
		SD	0.1289	0.1209
		Median	0.627	0.642
		Min.	0.42	0.35
		Max.	1.00	1.00
Day 29	SF-12 Score	n	89	75
		Mean	0.773	0.808
		SD	0.1442	0.1320
		Median	0.782	0.817
		Min.	0.42	0.49
		Max.	1.00	1.00
	Change from Baseline	n	77	67
		Mean	0.123	0.145
		SD	0.1536	0.1500
		Median	0.105	0.139
		Min.	-0.26	-0.14
		Max.	0.41	0.48

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	48.84	49.54
		SD	27.089	28.626
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	89	75
		Mean	76.47	78.33
		SD	25.283	23.884
		Median	81.25	87.50
		Min.	6.3	12.5
		Max.	100.0	100.0
	Change from Baseline	n	77	67
		Mean	28.90	27.61
		SD	30.129	29.338
		Median	25.00	25.00
		Min.	-56.3	-25.0
		Max.	87.5	87.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	38.78	39.03
		SD	9.732	10.285
		Median	39.19	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 29	SF-12 Score	n	89	75
		Mean	48.70	49.37
		SD	9.085	8.582
		Median	50.42	52.66
		Min.	23.5	25.7
		Max.	57.2	57.2
	Change from Baseline	n	77	67
		Mean	10.38	9.92
		SD	10.825	10.541
		Median	8.99	8.99
		Min.	-20.2	-9.0
		Max.	31.4	31.4

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	36.94	38.42
		SD	24.924	23.967
		Median	37.50	40.63
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	89	75
		Mean	58.29	63.33
		SD	26.328	21.683
		Median	56.25	62.50
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	77	67
		Mean	24.19	26.49
		SD	24.718	26.249
		Median	25.00	25.00
		Min.	-50.0	-18.8
		Max.	81.3	93.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.33
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	146	122
		Mean	40.45	41.15
		SD	11.848	11.393
		Median	40.72	42.21
		Min.	22.9	22.9
		Max.	70.4	70.4
Day 29	SF-12 Score	n	89	75
		Mean	50.60	52.99
		SD	12.514	10.306
		Median	49.63	52.60
		Min.	22.9	22.9
		Max.	70.4	70.4
	Change from Baseline	n	77	67
		Mean	11.50	12.59
		SD	11.749	12.477
		Median	11.89	11.88
		Min.	-23.8	-8.9
		Max.	38.6	44.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	96	98
n	26	30
LS Mean (SE)	88.54 (5.235)	80.46 (4.869)
95% C.I.	(78.25, 98.84)	(70.89, 90.04)
LS Mean Change from Baseline (SE)	29.62 (5.235)	21.55 (4.869)
95% C.I.	(19.33, 39.92)	(11.97, 31.12)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-8.08 (7.140)
95% C.I.		(-22.12, 5.96)
p-value		0.259
Corrected Hedge’s g (SE) [1]		-0.30 (0.269)
95% C.I.		(-0.83, 0.23)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Physical (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	26	30
LS Mean (SE)	75.86 (4.839)	80.17 (4.504)
95% C.I.	(66.35, 85.38)	(71.31, 89.03)
LS Mean Change from Baseline (SE)	25.47 (4.839)	29.78 (4.504)
95% C.I.	(15.96, 34.99)	(20.92, 38.63)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.31 (6.614)
95% C.I.		(-8.70, 17.31)
p-value		0.515
Corrected Hedge’s g (SE) [1]		0.17 (0.268)
95% C.I.		(-0.35, 0.70)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	26	30
LS Mean (SE)	85.61 (3.993)	79.76 (3.721)
95% C.I.	(77.75, 93.46)	(72.44, 87.07)
LS Mean Change from Baseline (SE)	23.66 (3.993)	17.81 (3.721)
95% C.I.	(15.81, 31.51)	(10.49, 25.13)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-5.85 (5.452)
95% C.I.		(-16.57, 4.87)
p-value		0.284
Corrected Hedge’s g (SE) [1]		-0.28 (0.269)
95% C.I.		(-0.81, 0.24)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: General Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	26	30
LS Mean (SE)	68.12 (3.868)	73.33 (3.605)
95% C.I.	(60.51, 75.72)	(66.24, 80.42)
LS Mean Change from Baseline (SE)	12.20 (3.868)	17.41 (3.605)
95% C.I.	(4.60, 19.81)	(10.33, 24.50)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		5.21 (5.290)
95% C.I.		(-5.19, 15.62)
p-value		0.325
Corrected Hedge’s g (SE) [1]		0.26 (0.269)
95% C.I.		(-0.27, 0.79)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Vitality (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	26	30
LS Mean (SE)	66.09 (5.797)	59.34 (5.427)
95% C.I.	(54.69, 77.49)	(48.67, 70.01)
LS Mean Change from Baseline (SE)	31.11 (5.797)	24.35 (5.427)
95% C.I.	(19.71, 42.51)	(13.68, 35.02)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-6.76 (7.911)
95% C.I.		(-22.31, 8.80)
p-value		0.394
Corrected Hedge’s g (SE) [1]		-0.22 (0.269)
95% C.I.		(-0.75, 0.30)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	26	30
LS Mean (SE)	84.53 (5.126)	82.24 (4.768)
95% C.I.	(74.45, 94.61)	(72.86, 91.61)
LS Mean Change from Baseline (SE)	36.29 (5.126)	34.00 (4.768)
95% C.I.	(26.21, 46.37)	(24.63, 43.38)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.29 (7.003)
95% C.I.		(-16.06, 11.48)
p-value		0.744
Corrected Hedge’s g (SE) [1]		-0.09 (0.268)
95% C.I.		(-0.61, 0.44)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	26	30
LS Mean (SE)	84.83 (4.311)	85.32 (4.005)
95% C.I.	(76.35, 93.31)	(77.44, 93.19)
LS Mean Change from Baseline (SE)	18.18 (4.311)	18.67 (4.005)
95% C.I.	(9.70, 26.66)	(10.80, 26.55)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.49 (5.873)
95% C.I.		(-11.06, 12.04)
p-value		0.934
Corrected Hedge’s g (SE) [1]		0.02 (0.268)
95% C.I.		(-0.50, 0.55)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Mental Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	26	30
LS Mean (SE)	76.63 (4.138)	76.14 (3.853)
95% C.I.	(68.50, 84.77)	(68.57, 83.72)
LS Mean Change from Baseline (SE)	18.24 (4.138)	17.76 (3.853)
95% C.I.	(10.11, 26.38)	(10.18, 25.33)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.49 (5.642)
95% C.I.		(-11.58, 10.61)
p-value		0.931
Corrected Hedge’s g (SE) [1]		-0.02 (0.268)
95% C.I.		(-0.55, 0.50)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Physical Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	26	30
LS Mean (SE)	51.64 (1.375)	50.92 (1.280)
95% C.I.	(48.94, 54.34)	(48.41, 53.44)
LS Mean Change from Baseline (SE)	7.85 (1.375)	7.14 (1.280)
95% C.I.	(5.15, 10.55)	(4.62, 9.65)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.72 (1.878)
95% C.I.		(-4.41, 2.98)
p-value		0.704
Corrected Hedge’s g (SE) [1]		-0.10 (0.268)
95% C.I.		(-0.63, 0.42)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Mental Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	26	30
LS Mean (SE)	52.54 (1.814)	52.20 (1.686)
95% C.I.	(48.97, 56.11)	(48.89, 55.52)
LS Mean Change from Baseline (SE)	9.77 (1.814)	9.43 (1.686)
95% C.I.	(6.20, 13.33)	(6.12, 12.75)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.33 (2.476)
95% C.I.		(-5.20, 4.53)
p-value		0.893
Corrected Hedge’s g (SE) [1]		-0.04 (0.268)
95% C.I.		(-0.56, 0.49)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Health Utility Index

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	26	30
LS Mean (SE)	0.81 (0.028)	0.80 (0.026)
95% C.I.	(0.76, 0.87)	(0.75, 0.85)
LS Mean Change from Baseline (SE)	0.17 (0.028)	0.15 (0.026)
95% C.I.	(0.11, 0.22)	(0.10, 0.21)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.01 (0.039)
95% C.I.		(-0.09, 0.06)
p-value		0.728
Corrected Hedge’s g (SE) [1]		-0.09 (0.268)
95% C.I.		(-0.62, 0.43)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	26	30
LS Mean (SE)	77.30 (4.485)	81.60 (4.175)
95% C.I.	(68.48, 86.12)	(73.39, 89.81)
LS Mean Change from Baseline (SE)	28.96 (4.485)	33.26 (4.175)
95% C.I.	(20.14, 37.78)	(25.05, 41.47)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.30 (6.127)
95% C.I.		(-7.75, 16.35)
p-value		0.483
Corrected Hedge’s g (SE) [1]		0.19 (0.269)
95% C.I.		(-0.34, 0.71)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	26	30
LS Mean (SE)	70.86 (4.445)	68.72 (4.137)
95% C.I.	(62.12, 79.60)	(60.59, 76.86)
LS Mean Change from Baseline (SE)	31.38 (4.445)	29.25 (4.137)
95% C.I.	(22.64, 40.12)	(21.11, 37.38)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.13 (6.065)
95% C.I.		(-14.06, 9.79)
p-value		0.725
Corrected Hedge’s g (SE) [1]		-0.09 (0.268)
95% C.I.		(-0.62, 0.43)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	84	72
n	37	29
LS Mean (SE)	82.72 (4.383)	89.98 (4.968)
95% C.I.	(74.10, 91.33)	(80.21, 99.75)
LS Mean Change from Baseline (SE)	23.80 (4.383)	31.06 (4.968)
95% C.I.	(15.18, 32.42)	(21.29, 40.83)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		7.26 (6.615)
95% C.I.		(-5.75, 20.27)
p-value		0.273
Corrected Hedge’s g (SE) [1]		0.27 (0.249)
95% C.I.		(-0.22, 0.76)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Physical (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	37	29
LS Mean (SE)	74.61 (4.055)	82.89 (4.605)
95% C.I.	(66.63, 82.58)	(73.83, 91.94)
LS Mean Change from Baseline (SE)	24.21 (4.055)	32.50 (4.605)
95% C.I.	(16.24, 32.19)	(23.44, 41.55)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		8.28 (6.132)
95% C.I.		(-3.78, 20.34)
p-value		0.178
Corrected Hedge’s g (SE) [1]		0.33 (0.250)
95% C.I.		(-0.16, 0.82)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	37	29
LS Mean (SE)	82.70 (3.345)	95.68 (3.800)
95% C.I.	(76.12, 89.27)	(88.21, 103.16)
LS Mean Change from Baseline (SE)	20.75 (3.345)	33.74 (3.800)
95% C.I.	(14.17, 27.33)	(26.27, 41.21)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		12.99 (5.059)
95% C.I.		(3.04, 22.94)
p-value		0.011
Corrected Hedge’s g (SE) [1]		0.63 (0.254)
95% C.I.		(0.13, 1.13)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: General Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	37	29
LS Mean (SE)	70.55 (3.241)	67.71 (3.666)
95% C.I.	(64.18, 76.93)	(60.50, 74.92)
LS Mean Change from Baseline (SE)	14.64 (3.241)	11.79 (3.666)
95% C.I.	(8.26, 21.01)	(4.58, 19.00)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.85 (4.893)
95% C.I.		(-12.47, 6.78)
p-value		0.561
Corrected Hedge’s g (SE) [1]		-0.14 (0.248)
95% C.I.		(-0.63, 0.34)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Vitality (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	37	29
LS Mean (SE)	67.87 (4.889)	80.28 (5.494)
95% C.I.	(58.26, 77.49)	(69.47, 91.08)
LS Mean Change from Baseline (SE)	32.89 (4.889)	45.29 (5.494)
95% C.I.	(23.27, 42.50)	(34.49, 56.09)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		12.40 (7.320)
95% C.I.		(-1.99, 26.80)
p-value		0.091
Corrected Hedge’s g (SE) [1]		0.41 (0.251)
95% C.I.		(-0.08, 0.90)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	37	29
LS Mean (SE)	76.49 (4.293)	87.35 (4.858)
95% C.I.	(68.05, 84.93)	(77.80, 96.90)
LS Mean Change from Baseline (SE)	28.25 (4.293)	39.11 (4.858)
95% C.I.	(19.81, 36.69)	(29.56, 48.66)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		10.86 (6.481)
95% C.I.		(-1.89, 23.60)
p-value		0.095
Corrected Hedge’s g (SE) [1]		0.41 (0.251)
95% C.I.		(-0.08, 0.90)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	37	29
LS Mean (SE)	80.44 (3.613)	87.71 (4.125)
95% C.I.	(73.34, 87.55)	(79.59, 95.82)
LS Mean Change from Baseline (SE)	13.80 (3.613)	21.06 (4.125)
95% C.I.	(6.69, 20.90)	(12.95, 29.17)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		7.27 (5.448)
95% C.I.		(-3.45, 17.98)
p-value		0.183
Corrected Hedge’s g (SE) [1]		0.33 (0.250)
95% C.I.		(-0.16, 0.81)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Mental Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	37	29
LS Mean (SE)	79.29 (3.468)	82.18 (3.927)
95% C.I.	(72.47, 86.10)	(74.46, 89.90)
LS Mean Change from Baseline (SE)	20.90 (3.468)	23.79 (3.927)
95% C.I.	(14.08, 27.72)	(16.07, 31.51)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.89 (5.224)
95% C.I.		(-7.38, 13.17)
p-value		0.580
Corrected Hedge’s g (SE) [1]		0.14 (0.248)
95% C.I.		(-0.35, 0.62)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Physical Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	37	29
LS Mean (SE)	50.70 (1.152)	53.36 (1.305)
95% C.I.	(48.43, 52.97)	(50.79, 55.92)
LS Mean Change from Baseline (SE)	6.91 (1.152)	9.57 (1.305)
95% C.I.	(4.65, 9.18)	(7.00, 12.13)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.66 (1.742)
95% C.I.		(-0.77, 6.08)
p-value		0.128
Corrected Hedge’s g (SE) [1]		0.37 (0.250)
95% C.I.		(-0.12, 0.86)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Mental Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	37	29
LS Mean (SE)	52.26 (1.519)	55.18 (1.721)
95% C.I.	(49.28, 55.25)	(51.80, 58.57)
LS Mean Change from Baseline (SE)	9.49 (1.519)	12.41 (1.721)
95% C.I.	(6.51, 12.48)	(9.02, 15.79)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.92 (2.293)
95% C.I.		(-1.59, 7.42)
p-value		0.204
Corrected Hedge’s g (SE) [1]		0.31 (0.249)
95% C.I.		(-0.18, 0.80)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Health Utility Index

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	37	29
LS Mean (SE)	0.79 (0.024)	0.88 (0.027)
95% C.I.	(0.74, 0.83)	(0.83, 0.94)
LS Mean Change from Baseline (SE)	0.14 (0.024)	0.24 (0.027)
95% C.I.	(0.09, 0.19)	(0.19, 0.29)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.10 (0.036)
95% C.I.		(0.03, 0.17)
p-value		0.006
Corrected Hedge’s g (SE) [1]		0.68 (0.255)
95% C.I.		(0.18, 1.18)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	37	29
LS Mean (SE)	76.00 (3.760)	85.00 (4.269)
95% C.I.	(68.60, 83.39)	(76.61, 93.40)
LS Mean Change from Baseline (SE)	27.66 (3.760)	36.67 (4.269)
95% C.I.	(20.27, 35.05)	(28.27, 45.06)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		9.01 (5.693)
95% C.I.		(-2.19, 20.20)
p-value		0.115
Corrected Hedge’s g (SE) [1]		0.39 (0.250)
95% C.I.		(-0.10, 0.88)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	37	29
LS Mean (SE)	72.75 (3.738)	81.28 (4.207)
95% C.I.	(65.40, 80.10)	(73.00, 89.55)
LS Mean Change from Baseline (SE)	33.28 (3.738)	41.80 (4.207)
95% C.I.	(25.93, 40.63)	(33.53, 50.08)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		8.52 (5.616)
95% C.I.		(-2.52, 19.57)
p-value		0.130
Corrected Hedge’s g (SE) [1]		0.37 (0.250)
95% C.I.		(-0.12, 0.86)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	58	64
n	33	25
LS Mean (SE)	82.80 (4.643)	88.16 (5.340)
95% C.I.	(73.67, 91.93)	(77.66, 98.66)
LS Mean Change from Baseline (SE)	23.88 (4.643)	29.24 (5.340)
95% C.I.	(14.75, 33.01)	(18.74, 39.74)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		5.36 (7.085)
95% C.I.		(-8.57, 19.29)
p-value		0.450
Corrected Hedge’s g (SE) [1]		0.20 (0.266)
95% C.I.		(-0.32, 0.72)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Physical (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	33	25
LS Mean (SE)	79.13 (4.295)	86.55 (4.940)
95% C.I.	(70.68, 87.58)	(76.84, 96.27)
LS Mean Change from Baseline (SE)	28.74 (4.295)	36.16 (4.940)
95% C.I.	(20.29, 37.18)	(26.45, 45.87)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		7.42 (6.552)
95% C.I.		(-5.46, 20.31)
p-value		0.258
Corrected Hedge’s g (SE) [1]		0.30 (0.267)
95% C.I.		(-0.23, 0.82)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	33	25
LS Mean (SE)	87.54 (3.546)	93.45 (4.070)
95% C.I.	(80.56, 94.51)	(85.45, 101.46)
LS Mean Change from Baseline (SE)	25.59 (3.546)	31.51 (4.070)
95% C.I.	(18.62, 32.56)	(23.51, 39.51)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		5.92 (5.400)
95% C.I.		(-4.70, 16.54)
p-value		0.274
Corrected Hedge’s g (SE) [1]		0.29 (0.266)
95% C.I.		(-0.24, 0.81)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: General Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	33	25
LS Mean (SE)	73.06 (3.432)	65.40 (3.950)
95% C.I.	(66.31, 79.81)	(57.63, 73.17)
LS Mean Change from Baseline (SE)	17.14 (3.432)	9.48 (3.950)
95% C.I.	(10.39, 23.89)	(1.72, 17.25)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-7.66 (5.235)
95% C.I.		(-17.95, 2.63)
p-value		0.144
Corrected Hedge’s g (SE) [1]		-0.38 (0.268)
95% C.I.		(-0.91, 0.14)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Vitality (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	33	25
LS Mean (SE)	65.20 (5.136)	77.02 (5.903)
95% C.I.	(55.10, 75.30)	(65.41, 88.63)
LS Mean Change from Baseline (SE)	30.21 (5.136)	42.03 (5.903)
95% C.I.	(20.11, 40.31)	(30.43, 53.64)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		11.82 (7.825)
95% C.I.		(-3.56, 27.21)
p-value		0.132
Corrected Hedge’s g (SE) [1]		0.40 (0.268)
95% C.I.		(-0.13, 0.92)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	33	25
LS Mean (SE)	83.72 (4.547)	86.30 (5.226)
95% C.I.	(74.78, 92.66)	(76.02, 96.57)
LS Mean Change from Baseline (SE)	35.48 (4.547)	38.06 (5.226)
95% C.I.	(26.54, 44.42)	(27.78, 48.33)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.58 (6.924)
95% C.I.		(-11.04, 16.19)
p-value		0.710
Corrected Hedge’s g (SE) [1]		0.10 (0.265)
95% C.I.		(-0.42, 0.62)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	33	25
LS Mean (SE)	87.03 (3.818)	93.30 (4.392)
95% C.I.	(79.52, 94.54)	(84.66, 101.94)
LS Mean Change from Baseline (SE)	20.38 (3.818)	26.66 (4.392)
95% C.I.	(12.88, 27.89)	(18.02, 35.29)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		6.27 (5.810)
95% C.I.		(-5.15, 17.70)
p-value		0.281
Corrected Hedge’s g (SE) [1]		0.28 (0.266)
95% C.I.		(-0.24, 0.80)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Mental Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	33	25
LS Mean (SE)	78.58 (3.665)	84.60 (4.213)
95% C.I.	(71.37, 85.79)	(76.32, 92.89)
LS Mean Change from Baseline (SE)	20.19 (3.665)	26.22 (4.213)
95% C.I.	(12.98, 27.40)	(17.93, 34.50)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		6.03 (5.584)
95% C.I.		(-4.95, 17.00)
p-value		0.281
Corrected Hedge’s g (SE) [1]		0.28 (0.266)
95% C.I.		(-0.24, 0.80)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Physical Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	33	25
LS Mean (SE)	51.38 (1.223)	52.30 (1.404)
95% C.I.	(48.97, 53.78)	(49.54, 55.06)
LS Mean Change from Baseline (SE)	7.59 (1.223)	8.51 (1.404)
95% C.I.	(5.18, 9.99)	(5.75, 11.27)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.92 (1.865)
95% C.I.		(-2.75, 4.59)
p-value		0.623
Corrected Hedge’s g (SE) [1]		0.13 (0.265)
95% C.I.		(-0.39, 0.65)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Mental Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	33	25
LS Mean (SE)	53.19 (1.609)	56.14 (1.848)
95% C.I.	(50.03, 56.35)	(52.51, 59.77)
LS Mean Change from Baseline (SE)	10.42 (1.609)	13.37 (1.848)
95% C.I.	(7.25, 13.58)	(9.73, 17.00)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.95 (2.449)
95% C.I.		(-1.87, 7.76)
p-value		0.229
Corrected Hedge’s g (SE) [1]		0.31 (0.267)
95% C.I.		(-0.21, 0.84)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Health Utility Index

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	33	25
LS Mean (SE)	0.84 (0.025)	0.88 (0.029)
95% C.I.	(0.79, 0.89)	(0.82, 0.94)
LS Mean Change from Baseline (SE)	0.19 (0.025)	0.24 (0.029)
95% C.I.	(0.14, 0.24)	(0.18, 0.29)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.04 (0.038)
95% C.I.		(-0.03, 0.12)
p-value		0.257
Corrected Hedge’s g (SE) [1]		0.30 (0.267)
95% C.I.		(-0.23, 0.82)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	33	25
LS Mean (SE)	81.31 (3.982)	87.86 (4.579)
95% C.I.	(73.48, 89.14)	(78.86, 96.87)
LS Mean Change from Baseline (SE)	32.97 (3.982)	39.53 (4.579)
95% C.I.	(25.14, 40.80)	(30.52, 48.53)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		6.56 (6.073)
95% C.I.		(-5.39, 18.50)
p-value		0.281
Corrected Hedge’s g (SE) [1]		0.28 (0.266)
95% C.I.		(-0.24, 0.80)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	33	25
LS Mean (SE)	71.05 (3.942)	80.30 (4.529)
95% C.I.	(63.30, 78.80)	(71.39, 89.21)
LS Mean Change from Baseline (SE)	31.58 (3.942)	40.82 (4.529)
95% C.I.	(23.83, 39.33)	(31.92, 49.73)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		9.25 (6.007)
95% C.I.		(-2.56, 21.06)
p-value		0.125
Corrected Hedge’s g (SE) [1]		0.40 (0.268)
95% C.I.		(-0.12, 0.93)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	60	74
n	24	35
LS Mean (SE)	83.59 (5.443)	80.87 (4.508)
95% C.I.	(72.89, 94.29)	(72.01, 89.74)
LS Mean Change from Baseline (SE)	24.67 (5.443)	21.95 (4.508)
95% C.I.	(13.97, 35.37)	(13.09, 30.82)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.72 (7.073)
95% C.I.		(-16.63, 11.19)
p-value		0.701
Corrected Hedge’s g (SE) [1]		-0.10 (0.265)
95% C.I.		(-0.62, 0.42)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Physical (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	24	35
LS Mean (SE)	81.24 (5.035)	81.57 (4.172)
95% C.I.	(71.34, 91.14)	(73.36, 89.77)
LS Mean Change from Baseline (SE)	30.85 (5.035)	31.18 (4.172)
95% C.I.	(20.95, 40.75)	(22.97, 39.38)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.32 (6.541)
95% C.I.		(-12.54, 13.19)
p-value		0.960
Corrected Hedge’s g (SE) [1]		0.01 (0.265)
95% C.I.		(-0.51, 0.53)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	24	35
LS Mean (SE)	99.07 (4.153)	90.34 (3.440)
95% C.I.	(90.91, 107.24)	(83.57, 97.10)
LS Mean Change from Baseline (SE)	37.13 (4.153)	28.39 (3.440)
95% C.I.	(28.96, 45.29)	(21.63, 35.15)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-8.74 (5.393)
95% C.I.		(-19.34, 1.87)
p-value		0.106
Corrected Hedge’s g (SE) [1]		-0.42 (0.268)
95% C.I.		(-0.95, 0.10)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: General Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	24	35
LS Mean (SE)	76.57 (4.028)	71.14 (3.345)
95% C.I.	(68.65, 84.49)	(64.56, 77.72)
LS Mean Change from Baseline (SE)	20.65 (4.028)	15.23 (3.345)
95% C.I.	(12.73, 28.57)	(8.65, 21.80)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-5.43 (5.244)
95% C.I.		(-15.74, 4.89)
p-value		0.301
Corrected Hedge’s g (SE) [1]		-0.27 (0.266)
95% C.I.		(-0.79, 0.25)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Vitality (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	24	35
LS Mean (SE)	56.16 (6.031)	70.94 (4.988)
95% C.I.	(44.30, 68.02)	(61.13, 80.74)
LS Mean Change from Baseline (SE)	21.17 (6.031)	35.95 (4.988)
95% C.I.	(9.31, 33.03)	(26.14, 45.76)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		14.78 (7.830)
95% C.I.		(-0.62, 30.18)
p-value		0.060
Corrected Hedge’s g (SE) [1]		0.49 (0.269)
95% C.I.		(-0.03, 1.02)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	24	35
LS Mean (SE)	85.12 (5.341)	87.04 (4.427)
95% C.I.	(74.62, 95.62)	(78.33, 95.74)
LS Mean Change from Baseline (SE)	36.88 (5.341)	38.80 (4.427)
95% C.I.	(26.38, 47.38)	(30.10, 47.51)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		1.92 (6.954)
95% C.I.		(-11.75, 15.59)
p-value		0.783
Corrected Hedge’s g (SE) [1]		0.07 (0.265)
95% C.I.		(-0.45, 0.59)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	24	35
LS Mean (SE)	90.21 (4.492)	86.92 (3.710)
95% C.I.	(81.38, 99.04)	(79.62, 94.21)
LS Mean Change from Baseline (SE)	23.56 (4.492)	20.27 (3.710)
95% C.I.	(14.73, 32.40)	(12.98, 27.57)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-3.29 (5.810)
95% C.I.		(-14.71, 8.13)
p-value		0.572
Corrected Hedge’s g (SE) [1]		-0.15 (0.265)
95% C.I.		(-0.67, 0.37)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Mental Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	24	35
LS Mean (SE)	76.66 (4.299)	80.39 (3.559)
95% C.I.	(68.21, 85.11)	(73.40, 87.39)
LS Mean Change from Baseline (SE)	18.27 (4.299)	22.01 (3.559)
95% C.I.	(9.82, 26.72)	(15.01, 29.00)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.73 (5.581)
95% C.I.		(-7.24, 14.71)
p-value		0.504
Corrected Hedge’s g (SE) [1]		0.18 (0.266)
95% C.I.		(-0.35, 0.70)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Physical Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	24	35
LS Mean (SE)	53.61 (1.432)	51.66 (1.185)
95% C.I.	(50.80, 56.43)	(49.33, 53.99)
LS Mean Change from Baseline (SE)	9.83 (1.432)	7.87 (1.185)
95% C.I.	(7.01, 12.64)	(5.54, 10.20)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-1.96 (1.859)
95% C.I.		(-5.61, 1.70)
p-value		0.293
Corrected Hedge’s g (SE) [1]		-0.28 (0.266)
95% C.I.		(-0.80, 0.25)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Mental Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	24	35
LS Mean (SE)	51.92 (1.891)	54.49 (1.561)
95% C.I.	(48.20, 55.64)	(51.42, 57.56)
LS Mean Change from Baseline (SE)	9.15 (1.891)	11.72 (1.561)
95% C.I.	(5.43, 12.87)	(8.65, 14.79)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.57 (2.453)
95% C.I.		(-2.25, 7.39)
p-value		0.296
Corrected Hedge’s g (SE) [1]		0.27 (0.266)
95% C.I.		(-0.25, 0.80)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Health Utility Index

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	24	35
LS Mean (SE)	0.81 (0.030)	0.84 (0.024)
95% C.I.	(0.76, 0.87)	(0.79, 0.89)
LS Mean Change from Baseline (SE)	0.17 (0.030)	0.20 (0.024)
95% C.I.	(0.11, 0.23)	(0.15, 0.24)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.03 (0.038)
95% C.I.		(-0.05, 0.10)
p-value		0.500
Corrected Hedge’s g (SE) [1]		0.18 (0.266)
95% C.I.		(-0.34, 0.70)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	24	35
LS Mean (SE)	83.34 (4.668)	83.11 (3.867)
95% C.I.	(74.16, 92.52)	(75.51, 90.72)
LS Mean Change from Baseline (SE)	35.00 (4.668)	34.78 (3.867)
95% C.I.	(25.82, 44.18)	(27.17, 42.38)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.23 (6.060)
95% C.I.		(-12.14, 11.69)
p-value		0.970
Corrected Hedge’s g (SE) [1]		-0.01 (0.265)
95% C.I.		(-0.53, 0.51)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	24	35
LS Mean (SE)	71.62 (4.625)	74.95 (3.826)
95% C.I.	(62.52, 80.71)	(67.42, 82.47)
LS Mean Change from Baseline (SE)	32.14 (4.625)	35.47 (3.826)
95% C.I.	(23.05, 41.23)	(27.95, 43.00)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.33 (6.004)
95% C.I.		(-8.47, 15.14)
p-value		0.579
Corrected Hedge’s g (SE) [1]		0.15 (0.265)
95% C.I.		(-0.37, 0.67)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	183	159
n	77	67
LS Mean (SE)	73.68 (3.063)	71.90 (3.255)
95% C.I.	(67.66, 79.70)	(65.50, 78.30)
LS Mean Change from Baseline (SE)	14.76 (3.063)	12.98 (3.255)
95% C.I.	(8.74, 20.79)	(6.58, 19.39)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-1.78 (4.469)
95% C.I.		(-10.56, 7.01)
p-value		0.691
Corrected Hedge’s g (SE) [1]		-0.07 (0.167)
95% C.I.		(-0.39, 0.26)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Physical (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	77	67
LS Mean (SE)	77.14 (2.813)	72.97 (3.014)
95% C.I.	(71.61, 82.67)	(67.04, 78.90)
LS Mean Change from Baseline (SE)	26.74 (2.813)	22.58 (3.014)
95% C.I.	(21.21, 32.28)	(16.65, 28.51)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-4.16 (4.120)
95% C.I.		(-12.27, 3.94)
p-value		0.313
Corrected Hedge’s g (SE) [1]		-0.17 (0.167)
95% C.I.		(-0.50, 0.16)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	77	67
LS Mean (SE)	85.74 (2.321)	86.27 (2.491)
95% C.I.	(81.18, 90.31)	(81.37, 91.17)
LS Mean Change from Baseline (SE)	23.80 (2.321)	24.33 (2.491)
95% C.I.	(19.23, 28.36)	(19.43, 29.22)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.53 (3.400)
95% C.I.		(-6.16, 7.21)
p-value		0.876
Corrected Hedge’s g (SE) [1]		0.03 (0.167)
95% C.I.		(-0.30, 0.35)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: General Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	77	67
LS Mean (SE)	69.84 (2.250)	65.66 (2.414)
95% C.I.	(65.42, 74.27)	(60.91, 70.40)
LS Mean Change from Baseline (SE)	13.93 (2.250)	9.74 (2.414)
95% C.I.	(9.50, 18.35)	(5.00, 14.49)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-4.19 (3.294)
95% C.I.		(-10.66, 2.29)
p-value		0.205
Corrected Hedge’s g (SE) [1]		-0.21 (0.168)
95% C.I.		(-0.54, 0.12)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Vitality (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	77	67
LS Mean (SE)	52.54 (3.395)	55.73 (3.614)
95% C.I.	(45.86, 59.21)	(48.63, 62.84)
LS Mean Change from Baseline (SE)	17.55 (3.395)	20.75 (3.614)
95% C.I.	(10.87, 24.22)	(13.64, 27.85)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.20 (4.933)
95% C.I.		(-6.50, 12.90)
p-value		0.517
Corrected Hedge’s g (SE) [1]		0.11 (0.167)
95% C.I.		(-0.22, 0.43)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	77	67
LS Mean (SE)	80.22 (2.976)	84.48 (3.194)
95% C.I.	(74.37, 86.07)	(78.20, 90.76)
LS Mean Change from Baseline (SE)	31.98 (2.976)	36.25 (3.194)
95% C.I.	(26.13, 37.84)	(29.96, 42.53)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.26 (4.366)
95% C.I.		(-4.32, 12.84)
p-value		0.330
Corrected Hedge’s g (SE) [1]		0.16 (0.167)
95% C.I.		(-0.17, 0.49)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	77	67
LS Mean (SE)	83.21 (2.507)	85.02 (2.700)
95% C.I.	(78.28, 88.14)	(79.71, 90.33)
LS Mean Change from Baseline (SE)	16.56 (2.507)	18.38 (2.700)
95% C.I.	(11.63, 21.49)	(13.07, 23.68)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		1.81 (3.662)
95% C.I.		(-5.39, 9.01)
p-value		0.621
Corrected Hedge’s g (SE) [1]		0.08 (0.167)
95% C.I.		(-0.25, 0.41)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Mental Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	77	67
LS Mean (SE)	70.67 (2.406)	76.54 (2.595)
95% C.I.	(65.94, 75.40)	(71.44, 81.64)
LS Mean Change from Baseline (SE)	12.28 (2.406)	18.15 (2.595)
95% C.I.	(7.55, 17.01)	(13.05, 23.25)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		5.87 (3.521)
95% C.I.		(-1.06, 12.79)
p-value		0.096
Corrected Hedge’s g (SE) [1]		0.28 (0.168)
95% C.I.		(-0.05, 0.60)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Physical Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	77	67
LS Mean (SE)	50.48 (0.801)	48.82 (0.856)
95% C.I.	(48.90, 52.05)	(47.14, 50.51)
LS Mean Change from Baseline (SE)	6.69 (0.801)	5.03 (0.856)
95% C.I.	(5.11, 8.26)	(3.35, 6.72)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-1.65 (1.173)
95% C.I.		(-3.96, 0.65)
p-value		0.159
Corrected Hedge’s g (SE) [1]		-0.23 (0.168)
95% C.I.		(-0.56, 0.09)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Mental Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	77	67
LS Mean (SE)	49.96 (1.053)	52.57 (1.136)
95% C.I.	(47.89, 52.03)	(50.34, 54.81)
LS Mean Change from Baseline (SE)	7.19 (1.053)	9.80 (1.136)
95% C.I.	(5.12, 9.26)	(7.57, 12.03)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.61 (1.548)
95% C.I.		(-0.43, 5.66)
p-value		0.092
Corrected Hedge’s g (SE) [1]		0.28 (0.168)
95% C.I.		(-0.05, 0.61)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Health Utility Index

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	77	67
LS Mean (SE)	0.78 (0.017)	0.80 (0.018)
95% C.I.	(0.74, 0.81)	(0.77, 0.83)
LS Mean Change from Baseline (SE)	0.13 (0.017)	0.16 (0.018)
95% C.I.	(0.10, 0.16)	(0.12, 0.19)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.02 (0.024)
95% C.I.		(-0.02, 0.07)
p-value		0.308
Corrected Hedge’s g (SE) [1]		0.17 (0.167)
95% C.I.		(-0.16, 0.50)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	77	67
LS Mean (SE)	77.68 (2.606)	76.89 (2.794)
95% C.I.	(72.55, 82.80)	(71.40, 82.39)
LS Mean Change from Baseline (SE)	29.34 (2.606)	28.56 (2.794)
95% C.I.	(24.22, 34.47)	(23.06, 34.05)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.78 (3.820)
95% C.I.		(-8.30, 6.73)
p-value		0.837
Corrected Hedge’s g (SE) [1]		-0.03 (0.167)
95% C.I.		(-0.36, 0.29)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.34
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	77	67
LS Mean (SE)	60.80 (2.590)	64.12 (2.769)
95% C.I.	(55.71, 65.89)	(58.68, 69.57)
LS Mean Change from Baseline (SE)	21.33 (2.590)	24.65 (2.769)
95% C.I.	(16.24, 26.42)	(19.20, 30.09)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.32 (3.783)
95% C.I.		(-4.12, 10.76)
p-value		0.381
Corrected Hedge’s g (SE) [1]		0.15 (0.167)
95% C.I.		(-0.18, 0.47)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.35
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Baseline Viral Load - GBA Approach

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	96	98
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	16 (17%)	15 (15%)
Non-responder	10 (10%)	15 (15%)
Missing [1]	70 (73%)	68 (69%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.11
95% C.I.		(0.51, 2.39)
p-value		0.797
Inverse Relative Risk [3]		1.09
95% C.I.		(0.57, 2.08)
p-value		0.797
Risk Difference (%) [4]		1.36
95% C.I.		(-8.95, 11.68)
p-value		0.847

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

PPD

Table 24.35
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Baseline Viral Load - GBA Approach

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	84	72
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	18 (21%)	23 (32%)
Non-responder	19 (23%)	6 (8%)
Missing [1]	47 (56%)	43 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.58
95% C.I.		(0.28, 1.19)
p-value		0.139
Inverse Relative Risk [3]		0.67
95% C.I.		(0.39, 1.14)
p-value		0.141
Risk Difference (%) [4]		-10.52
95% C.I.		(-24.41, 3.38)
p-value		0.149

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

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Table 24.35
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Baseline Viral Load - GBA Approach

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	58	64
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	16 (28%)	15 (23%)
Non-responder	17 (29%)	10 (16%)
Missing [1]	25 (43%)	39 (61%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.24
95% C.I.		(0.55, 2.81)
p-value		0.600
Inverse Relative Risk [3]		1.18
95% C.I.		(0.64, 2.16)
p-value		0.600
Risk Difference (%) [4]		4.15
95% C.I.		(-11.34, 19.64)
p-value		0.679

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

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Table 24.35
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Baseline Viral Load - GBA Approach

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	60	74
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	9 (15%)	19 (26%)
Non-responder	15 (25%)	16 (22%)
Missing [1]	36 (60%)	39 (53%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.51
95% C.I.		(0.21, 1.23)
p-value		0.135
Inverse Relative Risk [3]		0.58
95% C.I.		(0.29, 1.20)
p-value		0.142
Risk Difference (%) [4]		-10.68
95% C.I.		(-24.12, 2.77)
p-value		0.142

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

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Table 24.35
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Baseline Viral Load - GBA Approach

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	183	159
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	25 (14%)	28 (18%)
Non-responder	52 (28%)	39 (25%)
Missing [1]	106 (58%)	92 (58%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.74
95% C.I.		(0.41, 1.33)
p-value		0.316
Inverse Relative Risk [3]		0.78
95% C.I.		(0.47, 1.27)
p-value		0.316
Risk Difference (%) [4]		-3.95
95% C.I.		(-11.68, 3.79)
p-value		0.370

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

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Table 24.36
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Baseline Viral Load - GBA Approach

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	96	98
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	12 (13%)	14 (14%)
Non-responder	14 (15%)	16 (16%)
Missing [1]	70 (73%)	68 (69%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.86
95% C.I.		(0.37, 1.96)
p-value		0.716
Inverse Relative Risk [3]		0.88
95% C.I.		(0.43, 1.79)
p-value		0.716
Risk Difference (%) [4]		-1.79
95% C.I.		(-11.37, 7.79)
p-value		0.834

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

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Table 24.36
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Baseline Viral Load - GBA Approach

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	84	72
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	15 (18%)	20 (28%)
Non-responder	22 (26%)	9 (13%)
Missing [1]	47 (56%)	43 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.57
95% C.I.		(0.26, 1.21)
p-value		0.142
Inverse Relative Risk [3]		0.64
95% C.I.		(0.36, 1.16)
p-value		0.143
Risk Difference (%) [4]		-9.92
95% C.I.		(-23.12, 3.27)
p-value		0.178

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

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Table 24.36
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Baseline Viral Load - GBA Approach

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	58	64
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	10 (17%)	14 (22%)
Non-responder	23 (40%)	11 (17%)
Missing [1]	25 (43%)	39 (61%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.74
95% C.I.		(0.30, 1.84)
p-value		0.522
Inverse Relative Risk [3]		0.79
95% C.I.		(0.38, 1.63)
p-value		0.523
Risk Difference (%) [4]		-4.63
95% C.I.		(-18.67, 9.40)
p-value		0.650

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

PPD

Table 24.36
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Baseline Viral Load - GBA Approach

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	60	74
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	12 (20%)	15 (20%)
Non-responder	12 (20%)	20 (27%)
Missing [1]	36 (60%)	39 (53%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.98
95% C.I.		(0.42, 2.30)
p-value		0.970
Inverse Relative Risk [3]		0.99
95% C.I.		(0.50, 1.94)
p-value		0.970
Risk Difference (%) [4]		-0.27
95% C.I.		(-13.92, 13.38)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

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Table 24.36
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Baseline Viral Load - GBA Approach

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	183	159
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	26 (14%)	22 (14%)
Non-responder	51 (28%)	45 (28%)
Missing [1]	106 (58%)	92 (58%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.03
95% C.I.		(0.56, 1.90)
p-value		0.922
Inverse Relative Risk [3]		1.03
95% C.I.		(0.61, 1.74)
p-value		0.922
Risk Difference (%) [4]		0.37
95% C.I.		(-7.00, 7.75)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

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Table 24.37
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Baseline Viral Load - QualityMetric Approach

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	96	98
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	17 (18%)	17 (17%)
Non-responder	9 (9%)	13 (13%)
Missing [1]	70 (73%)	68 (69%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.03
95% C.I.		(0.49, 2.15)
p-value		0.948
Inverse Relative Risk [3]		1.02
95% C.I.		(0.55, 1.88)
p-value		0.948
Risk Difference (%) [4]		0.36
95% C.I.		(-10.34, 11.06)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

PPD

Table 24.37
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Baseline Viral Load - QualityMetric Approach

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	84	72
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	19 (23%)	23 (32%)
Non-responder	18 (21%)	6 (8%)
Missing [1]	47 (56%)	43 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.62
95% C.I.		(0.31, 1.27)
p-value		0.193
Inverse Relative Risk [3]		0.71
95% C.I.		(0.42, 1.19)
p-value		0.193
Risk Difference (%) [4]		-9.33
95% C.I.		(-23.33, 4.68)
p-value		0.209

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

PPD

Table 24.37
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Baseline Viral Load - QualityMetric Approach

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	58	64
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	20 (34%)	17 (27%)
Non-responder	13 (22%)	8 (13%)
Missing [1]	25 (43%)	39 (61%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.46
95% C.I.		(0.67, 3.16)
p-value		0.343
Inverse Relative Risk [3]		1.30
95% C.I.		(0.76, 2.23)
p-value		0.344
Risk Difference (%) [4]		7.92
95% C.I.		(-8.41, 24.25)
p-value		0.431

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

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Population: Intent-to-Treat Data as of 27APR2021

Table 24.37
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Baseline Viral Load - QualityMetric Approach

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	60	74
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	10 (17%)	21 (28%)
Non-responder	14 (23%)	14 (19%)
Missing [1]	36 (60%)	39 (53%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.50
95% C.I.		(0.22, 1.18)
p-value		0.114
Inverse Relative Risk [3]		0.59
95% C.I.		(0.30, 1.15)
p-value		0.121
Risk Difference (%) [4]		-11.71
95% C.I.		(-25.66, 2.23)
p-value		0.150

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

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Population: Intent-to-Treat Data as of 27APR2021

Table 24.37
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Baseline Viral Load - QualityMetric Approach

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	183	159
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	37 (20%)	33 (21%)
Non-responder	40 (22%)	34 (21%)
Missing [1]	106 (58%)	92 (58%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.97
95% C.I.		(0.57, 1.64)
p-value		0.903
Inverse Relative Risk [3]		0.97
95% C.I.		(0.64, 1.48)
p-value		0.903
Risk Difference (%) [4]		-0.54
95% C.I.		(-9.12, 8.04)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.38
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Baseline Viral Load - QualityMetric Approach

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	96	98
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	15 (16%)	15 (15%)
Non-responder	11 (11%)	15 (15%)
Missing [1]	70 (73%)	68 (69%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.02
95% C.I.		(0.47, 2.23)
p-value		0.952
Inverse Relative Risk [3]		1.02
95% C.I.		(0.53, 1.97)
p-value		0.952
Risk Difference (%) [4]		0.32
95% C.I.		(-9.86, 10.50)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Table 24.38
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Baseline Viral Load - QualityMetric Approach

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	84	72
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	18 (21%)	20 (28%)
Non-responder	19 (23%)	9 (13%)
Missing [1]	47 (56%)	43 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.71
95% C.I.		(0.34, 1.48)
p-value		0.359
Inverse Relative Risk [3]		0.77
95% C.I.		(0.44, 1.34)
p-value		0.359
Risk Difference (%) [4]		-6.35
95% C.I.		(-19.92, 7.22)
p-value		0.455

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

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Table 24.38
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Baseline Viral Load - QualityMetric Approach

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	58	64
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	13 (22%)	17 (27%)
Non-responder	20 (34%)	8 (13%)
Missing [1]	25 (43%)	39 (61%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.80
95% C.I.		(0.35, 1.83)
p-value		0.596
Inverse Relative Risk [3]		0.84
95% C.I.		(0.45, 1.58)
p-value		0.597
Risk Difference (%) [4]		-4.15
95% C.I.		(-19.39, 11.09)
p-value		0.676

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Table 24.38
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Baseline Viral Load - QualityMetric Approach

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	60	74
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	17 (28%)	20 (27%)
Non-responder	7 (12%)	15 (20%)
Missing [1]	36 (60%)	39 (53%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.07
95% C.I.		(0.50, 2.28)
p-value		0.867
Inverse Relative Risk [3]		1.05
95% C.I.		(0.61, 1.82)
p-value		0.867
Risk Difference (%) [4]		1.31
95% C.I.		(-13.94, 16.55)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

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Table 24.38
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Baseline Viral Load - QualityMetric Approach

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	183	159
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	32 (17%)	28 (18%)
Non-responder	45 (25%)	39 (25%)
Missing [1]	106 (58%)	92 (58%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.99
95% C.I.		(0.57, 1.73)
p-value		0.977
Inverse Relative Risk [3]		0.99
95% C.I.		(0.63, 1.57)
p-value		0.977
Risk Difference (%) [4]		-0.12
95% C.I.		(-8.21, 7.96)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, baseline viral load category and baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		256	229
Baseline	SF-12 Score	n	191	176
		Mean	60.82	57.81
		SD	31.930	32.940
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	116	106
		Mean	82.76	84.91
		SD	24.981	26.877
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	98	91
		Mean	18.11	28.57
		SD	32.661	35.663
		Median	0.00	25.00
		Min.	-75.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	191	176
		Mean	44.73	43.78
		SD	10.052	10.370
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	116	106
		Mean	51.63	52.31
		SD	7.864	8.461
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	98	91
		Mean	5.70	8.99
		SD	10.282	11.227
		Median	0.00	7.87
		Min.	-23.6	-15.7
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	54.74	51.92
		SD	26.364	28.329
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	116	106
		Mean	78.23	83.02
		SD	24.513	25.599
		Median	75.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	98	91
		Mean	24.62	34.20
		SD	29.244	32.587
		Median	25.00	37.50
		Min.	-50.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	42.14	41.19
		SD	8.925	9.590
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	116	106
		Mean	50.09	51.71
		SD	8.297	8.665
		Median	49.00	57.46
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	98	91
		Mean	8.33	11.58
		SD	9.899	11.031
		Median	8.46	12.69
		Min.	-16.9	-16.9
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	63.95	60.09
		SD	30.039	29.177
		Median	75.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	116	106
		Mean	87.50	91.04
		SD	19.918	19.575
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	98	91
		Mean	24.49	33.79
		SD	28.032	32.355
		Median	25.00	25.00
		Min.	-50.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	44.72	43.33
		SD	10.837	10.526
		Median	48.71	39.69
		Min.	21.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	116	106
		Mean	53.22	54.50
		SD	7.186	7.062
		Median	57.73	57.73
		Min.	21.7	21.7
		Max.	57.7	57.7
	Change from Baseline	n	98	91
		Mean	8.84	12.19
		SD	10.114	11.673
		Median	9.02	9.02
		Min.	-18.0	-27.1
		Max.	36.1	36.1

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	191	176
		Mean	59.06	51.96
		SD	26.816	29.919
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	116	106
		Mean	70.78	72.59
		SD	20.061	18.762
		Median	60.00	60.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	98	91
		Mean	11.63	19.12
		SD	24.535	32.716
		Median	0.00	0.00
		Min.	-40.0	-60.0
		Max.	85.0	85.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	191	176
		Mean	47.38	44.56
		SD	10.661	11.894
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	116	106
		Mean	52.04	52.76
		SD	7.976	7.460
		Median	47.75	47.75
		Min.	33.8	23.9
		Max.	63.7	63.7
	Change from Baseline	n	98	91
		Mean	4.62	7.60
		SD	9.754	13.006
		Median	0.00	0.00
		Min.	-15.9	-23.9
		Max.	33.8	33.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	38.03	38.49
		SD	27.423	28.140
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	116	106
		Mean	64.44	73.58
		SD	28.581	28.417
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	98	91
		Mean	29.08	33.52
		SD	31.642	41.869
		Median	25.00	50.00
		Min.	-50.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	44.36	44.54
		SD	10.791	11.073
		Median	49.07	49.07
		Min.	29.4	29.4
		Max.	68.7	68.7
Day 29	SF-12 Score	n	116	106
		Mean	54.75	58.35
		SD	11.245	11.181
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	98	91
		Mean	11.44	13.19
		SD	12.450	16.475
		Median	9.84	19.67
		Min.	-19.7	-39.3
		Max.	39.3	39.3

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	51.32	46.73
		SD	35.424	34.744
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	116	106
		Mean	84.27	89.62
		SD	24.788	22.591
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	98	91
		Mean	30.36	45.05
		SD	38.033	38.046
		Median	25.00	50.00
		Min.	-50.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	39.58	37.95
		SD	12.604	12.362
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	116	106
		Mean	51.30	53.21
		SD	8.819	8.037
		Median	56.90	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	98	91
		Mean	10.80	16.03
		SD	13.531	13.537
		Median	8.90	17.79
		Min.	-17.8	-26.7
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	68.49	67.26
		SD	26.748	27.991
		Median	75.00	68.75
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	116	106
		Mean	86.53	89.74
		SD	21.503	22.743
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	98	91
		Mean	16.58	25.27
		SD	28.024	31.567
		Median	0.00	25.00
		Min.	-75.0	-50.0
		Max.	87.5	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	43.18	42.67
		SD	11.123	11.639
		Median	45.89	43.29
		Min.	14.7	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	116	106
		Mean	50.68	52.01
		SD	8.941	9.456
		Median	56.28	56.28
		Min.	14.7	14.7
		Max.	56.3	56.3
	Change from Baseline	n	98	91
		Mean	6.89	10.51
		SD	11.654	13.126
		Median	0.00	10.39
		Min.	-31.2	-20.8
		Max.	36.4	41.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	62.30	60.01
		SD	22.327	22.875
		Median	62.50	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	116	106
		Mean	77.05	79.95
		SD	21.299	19.646
		Median	87.50	87.50
		Min.	25.0	37.5
		Max.	100.0	100.0
	Change from Baseline	n	98	91
		Mean	14.67	22.66
		SD	25.826	30.443
		Median	12.50	12.50
		Min.	-37.5	-50.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	46.91	45.86
		SD	10.246	10.497
		Median	47.00	41.26
		Min.	18.3	18.3
		Max.	64.2	64.2
Day 29	SF-12 Score	n	116	106
		Mean	53.68	55.01
		SD	9.775	9.016
		Median	58.47	58.47
		Min.	29.8	35.5
		Max.	64.2	64.2
	Change from Baseline	n	98	91
		Mean	6.73	10.40
		SD	11.853	13.971
		Median	5.73	5.74
		Min.	-17.2	-23.0
		Max.	34.4	45.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	44.55	43.05
		SD	8.670	8.696
		Median	43.93	43.46
		Min.	17.4	20.2
		Max.	59.9	62.7
Day 29	SF-12 Score	n	116	106
		Mean	51.44	52.42
		SD	6.780	7.075
		Median	53.23	53.65
		Min.	28.5	26.1
		Max.	62.4	62.7
	Change from Baseline	n	98	91
		Mean	6.74	9.59
		SD	8.614	9.189
		Median	5.25	9.35
		Min.	-13.3	-10.4
		Max.	26.0	30.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	44.16	43.53
		SD	9.753	10.014
		Median	42.93	42.72
		Min.	17.0	15.9
		Max.	73.0	65.4
Day 29	SF-12 Score	n	116	106
		Mean	52.82	54.91
		SD	8.945	7.794
		Median	54.98	57.04
		Min.	25.6	29.0
		Max.	65.6	66.8
	Change from Baseline	n	98	91
		Mean	8.59	12.23
		SD	11.433	13.132
		Median	7.65	12.87
		Min.	-12.9	-20.6
		Max.	45.3	43.7

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	0.662	0.640
		SD	0.1315	0.1325
		Median	0.631	0.615
		Min.	0.35	0.35
		Max.	1.00	1.00
Day 29	SF-12 Score	n	116	106
		Mean	0.815	0.863
		SD	0.1408	0.1379
		Median	0.859	0.922
		Min.	0.49	0.48
		Max.	1.00	1.00
	Change from Baseline	n	98	91
		Mean	0.152	0.235
		SD	0.1581	0.1895
		Median	0.125	0.255
		Min.	-0.23	-0.26
		Max.	0.52	0.66

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	51.97	48.47
		SD	25.826	27.052
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	116	106
		Mean	79.85	84.67
		SD	22.813	23.340
		Median	87.50	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	98	91
		Mean	28.70	39.22
		SD	27.948	31.223
		Median	25.00	43.75
		Min.	-25.0	-25.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	39.90	38.64
		SD	9.279	9.719
		Median	39.19	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 29	SF-12 Score	n	116	106
		Mean	49.92	51.65
		SD	8.198	8.387
		Median	52.66	57.16
		Min.	21.2	21.2
		Max.	57.2	57.2
	Change from Baseline	n	98	91
		Mean	10.31	14.09
		SD	10.042	11.219
		Median	8.98	15.72
		Min.	-9.0	-9.0
		Max.	35.9	35.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	44.21	42.08
		SD	24.368	23.634
		Median	46.88	43.75
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	116	106
		Mean	70.74	77.59
		SD	22.701	20.700
		Median	68.75	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	98	91
		Mean	29.72	37.43
		SD	25.918	29.352
		Median	31.25	37.50
		Min.	-50.0	-31.3
		Max.	93.8	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	190	176
		Mean	43.91	42.89
		SD	11.583	11.235
		Median	45.18	43.69
		Min.	22.9	22.9
		Max.	70.4	70.4
Day 29	SF-12 Score	n	116	106
		Mean	56.52	59.77
		SD	10.789	9.837
		Median	55.57	58.54
		Min.	22.9	22.9
		Max.	70.4	70.4
	Change from Baseline	n	98	91
		Mean	14.13	17.79
		SD	12.319	13.951
		Median	14.85	17.83
		Min.	-23.8	-14.9
		Max.	44.6	47.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		273	299
Baseline	SF-12 Score	n	208	223
		Mean	52.10	56.84
		SD	34.546	33.403
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	141	135
		Mean	76.24	77.78
		SD	28.241	30.184
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	117	118
		Mean	21.27	19.28
		SD	38.594	39.143
		Median	25.00	25.00
		Min.	-50.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	41.98	43.47
		SD	10.875	10.515
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	141	135
		Mean	49.58	50.06
		SD	8.890	9.502
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	117	118
		Mean	6.70	6.07
		SD	12.149	12.322
		Median	7.87	7.87
		Min.	-15.7	-31.5
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	46.51	52.97
		SD	28.070	28.970
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	141	135
		Mean	75.44	78.61
		SD	25.107	25.775
		Median	75.00	87.50
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	117	118
		Mean	28.21	24.79
		SD	31.192	32.316
		Median	25.00	25.00
		Min.	-50.0	-62.5
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	39.36	41.54
		SD	9.503	9.807
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	141	135
		Mean	49.15	50.22
		SD	8.498	8.724
		Median	49.00	53.23
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	117	118
		Mean	9.55	8.39
		SD	10.559	10.939
		Median	8.46	8.46
		Min.	-16.9	-21.2
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	207	223
		Mean	60.63	61.32
		SD	28.546	30.814
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	141	135
		Mean	84.22	86.85
		SD	24.715	23.024
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	117	118
		Mean	22.44	22.67
		SD	31.892	29.776
		Median	25.00	25.00
		Min.	-50.0	-50.0
		Max.	100.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	207	223
		Mean	43.53	43.78
		SD	10.299	11.116
		Median	48.71	48.71
		Min.	21.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	141	135
		Mean	52.04	52.99
		SD	8.916	8.307
		Median	57.73	57.73
		Min.	21.7	21.7
		Max.	57.7	57.7
	Change from Baseline	n	117	118
		Mean	8.09	8.18
		SD	11.506	10.743
		Median	9.02	9.02
		Min.	-18.0	-18.0
		Max.	36.1	27.1

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	52.86	55.58
		SD	29.314	28.721
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	141	135
		Mean	70.96	65.56
		SD	20.873	21.087
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	117	118
		Mean	14.32	9.24
		SD	26.334	30.132
		Median	0.00	0.00
		Min.	-60.0	-100.0
		Max.	85.0	85.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	44.91	46.00
		SD	11.653	11.418
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	141	135
		Mean	52.11	49.96
		SD	8.299	8.384
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
	Change from Baseline	n	117	118
		Mean	5.69	3.67
		SD	10.469	11.980
		Median	0.00	0.00
		Min.	-23.8	-39.8
		Max.	33.8	33.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	34.98	34.87
		SD	28.333	27.737
		Median	25.00	25.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	141	134
		Mean	56.38	60.82
		SD	33.595	34.473
		Median	75.00	62.50
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	117	118
		Mean	22.01	24.79
		SD	31.854	36.176
		Median	25.00	25.00
		Min.	-50.0	-100.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	43.15	43.11
		SD	11.149	10.915
		Median	39.23	39.23
		Min.	29.4	29.4
		Max.	68.7	68.7
Day 29	SF-12 Score	n	141	134
		Mean	51.58	53.32
		SD	13.219	13.564
		Median	58.90	53.99
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	117	118
		Mean	8.66	9.75
		SD	12.534	14.235
		Median	9.83	9.84
		Min.	-19.7	-39.3
		Max.	29.5	39.3

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	43.03	46.75
		SD	36.025	36.960
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	141	135
		Mean	77.84	83.15
		SD	27.886	27.289
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	117	118
		Mean	35.47	34.96
		SD	40.503	41.749
		Median	25.00	37.50
		Min.	-75.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	36.63	37.95
		SD	12.817	13.151
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	141	135
		Mean	49.02	50.91
		SD	9.921	9.708
		Median	56.90	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	117	118
		Mean	12.62	12.44
		SD	14.410	14.854
		Median	8.90	13.35
		Min.	-26.7	-26.7
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	61.54	66.70
		SD	28.668	29.965
		Median	50.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	141	135
		Mean	81.74	86.39
		SD	24.436	21.943
		Median	100.00	100.00
		Min.	0.0	12.5
		Max.	100.0	100.0
	Change from Baseline	n	117	118
		Mean	19.02	18.11
		SD	28.362	31.120
		Median	12.50	6.25
		Min.	-50.0	-62.5
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	40.29	42.44
		SD	11.922	12.460
		Median	35.49	45.89
		Min.	14.7	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	141	135
		Mean	48.69	50.62
		SD	10.161	9.124
		Median	56.28	56.28
		Min.	14.7	19.9
		Max.	56.3	56.3
	Change from Baseline	n	117	118
		Mean	7.91	7.53
		SD	11.793	12.940
		Median	5.20	2.59
		Min.	-20.8	-26.0
		Max.	31.2	41.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	54.87	58.52
		SD	22.141	24.522
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	141	135
		Mean	72.70	76.94
		SD	22.639	22.592
		Median	75.00	87.50
		Min.	12.5	12.5
		Max.	100.0	100.0
	Change from Baseline	n	117	118
		Mean	17.63	19.39
		SD	26.166	29.033
		Median	12.50	12.50
		Min.	-37.5	-50.0
		Max.	75.0	87.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	43.50	45.17
		SD	10.161	11.253
		Median	41.26	41.26
		Min.	18.3	18.3
		Max.	64.2	64.2
Day 29	SF-12 Score	n	141	135
		Mean	51.68	53.63
		SD	10.389	10.368
		Median	52.74	58.47
		Min.	24.1	24.1
		Max.	64.2	64.2
	Change from Baseline	n	117	118
		Mean	8.09	8.90
		SD	12.009	13.324
		Median	5.74	5.74
		Min.	-17.2	-23.0
		Max.	34.4	40.1

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	42.76	43.70
		SD	9.450	9.089
		Median	43.61	43.93
		Min.	18.0	20.4
		Max.	62.6	64.6
Day 29	SF-12 Score	n	141	135
		Mean	50.63	50.21
		SD	7.797	8.494
		Median	51.74	53.46
		Min.	22.7	23.5
		Max.	65.3	69.4
	Change from Baseline	n	117	118
		Mean	7.03	5.81
		SD	9.095	9.171
		Median	5.82	5.37
		Min.	-12.9	-19.7
		Max.	35.6	28.8

Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	41.28	42.73
		SD	10.109	10.629
		Median	40.74	41.35
		Min.	13.8	11.0
		Max.	64.4	69.3
Day 29	SF-12 Score	n	141	135
		Mean	50.32	52.70
		SD	10.444	9.613
		Median	52.27	55.06
		Min.	16.0	20.4
		Max.	65.0	64.8
	Change from Baseline	n	117	118
		Mean	9.20	9.95
		SD	10.909	11.849
		Median	7.20	8.68
		Min.	-18.4	-16.0
		Max.	37.8	41.5

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	207	223
		Mean	0.625	0.643
		SD	0.1104	0.1292
		Median	0.615	0.630
		Min.	0.37	0.35
		Max.	0.92	1.00
Day 29	SF-12 Score	n	141	134
		Mean	0.772	0.815
		SD	0.1520	0.1570
		Median	0.768	0.817
		Min.	0.41	0.43
		Max.	1.00	1.00
	Change from Baseline	n	117	118
		Mean	0.152	0.162
		SD	0.1614	0.1742
		Median	0.122	0.140
		Min.	-0.26	-0.31
		Max.	0.52	0.50

Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	45.73	50.42
		SD	26.534	28.431
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	141	135
		Mean	76.51	80.74
		SD	23.927	23.940
		Median	81.25	93.75
		Min.	0.0	6.3
		Max.	100.0	100.0
	Change from Baseline	n	117	118
		Mean	30.18	29.40
		SD	28.680	30.315
		Median	31.25	28.13
		Min.	-56.3	-56.3
		Max.	93.8	100.0

Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	37.66	39.34
		SD	9.533	10.215
		Median	39.19	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 29	SF-12 Score	n	141	135
		Mean	48.72	50.24
		SD	8.598	8.603
		Median	50.42	54.91
		Min.	21.2	23.5
		Max.	57.2	57.2
	Change from Baseline	n	117	118
		Mean	10.84	10.56
		SD	10.304	10.892
		Median	11.22	10.10
		Min.	-20.2	-20.2
		Max.	33.7	35.9

Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	37.68	40.02
		SD	23.673	25.293
		Median	40.63	43.75
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	141	135
		Mean	64.01	68.35
		SD	27.057	27.285
		Median	62.50	68.75
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	117	118
		Mean	26.34	27.97
		SD	25.425	27.768
		Median	25.00	31.25
		Min.	-31.3	-50.0
		Max.	81.3	93.8

Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.44
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	208	223
		Mean	40.80	41.91
		SD	11.254	12.023
		Median	42.21	43.69
		Min.	22.9	22.9
		Max.	70.4	70.4
Day 29	SF-12 Score	n	141	135
		Mean	53.31	55.38
		SD	12.860	12.968
		Median	52.60	55.57
		Min.	22.9	22.9
		Max.	70.4	70.4
	Change from Baseline	n	117	118
		Mean	12.52	13.29
		SD	12.085	13.198
		Median	11.88	14.85
		Min.	-14.9	-23.8
		Max.	38.6	44.6

Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	256	229
n	98	91
LS Mean (SE)	82.23 (2.714)	85.30 (2.807)
95% C.I.	(76.90, 87.57)	(79.78, 90.82)
LS Mean Change from Baseline (SE)	23.13 (2.714)	26.19 (2.807)
95% C.I.	(17.79, 28.46)	(20.68, 31.71)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.07 (3.913)
95% C.I.		(-4.62, 10.76)
p-value		0.433
Corrected Hedge’s g (SE) [1]		0.11 (0.146)
95% C.I.		(-0.17, 0.40)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Role Physical (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	98	91
LS Mean (SE)	78.92 (2.456)	83.84 (2.544)
95% C.I.	(74.09, 83.75)	(78.84, 88.84)
LS Mean Change from Baseline (SE)	27.59 (2.456)	32.51 (2.544)
95% C.I.	(22.77, 32.42)	(27.51, 37.51)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.92 (3.541)
95% C.I.		(-2.04, 11.88)
p-value		0.165
Corrected Hedge’s g (SE) [1]		0.20 (0.146)
95% C.I.		(-0.08, 0.49)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	98	91
LS Mean (SE)	87.72 (2.142)	91.89 (2.231)
95% C.I.	(83.51, 91.93)	(87.51, 96.28)
LS Mean Change from Baseline (SE)	25.46 (2.142)	29.63 (2.231)
95% C.I.	(21.25, 29.67)	(25.25, 34.01)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.17 (3.095)
95% C.I.		(-1.91, 10.26)
p-value		0.179
Corrected Hedge’s g (SE) [1]		0.20 (0.146)
95% C.I.		(-0.09, 0.48)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: General Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	98	91
LS Mean (SE)	70.79 (1.977)	72.23 (2.053)
95% C.I.	(66.91, 74.68)	(68.20, 76.27)
LS Mean Change from Baseline (SE)	14.35 (1.977)	15.79 (2.053)
95% C.I.	(10.47, 18.24)	(11.76, 19.83)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		1.44 (2.857)
95% C.I.		(-4.17, 7.06)
p-value		0.614
Corrected Hedge’s g (SE) [1]		0.07 (0.146)
95% C.I.		(-0.21, 0.36)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Vitality (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	98	91
LS Mean (SE)	64.12 (3.080)	72.23 (3.202)
95% C.I.	(58.07, 70.18)	(65.93, 78.52)
LS Mean Change from Baseline (SE)	27.98 (3.080)	36.08 (3.202)
95% C.I.	(21.92, 34.03)	(29.79, 42.38)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		8.10 (4.448)
95% C.I.		(-0.64, 16.85)
p-value		0.069
Corrected Hedge’s g (SE) [1]		0.26 (0.146)
95% C.I.		(-0.02, 0.55)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	98	91
LS Mean (SE)	83.25 (2.615)	90.91 (2.704)
95% C.I.	(78.11, 88.40)	(85.59, 96.22)
LS Mean Change from Baseline (SE)	35.91 (2.615)	43.56 (2.704)
95% C.I.	(30.77, 41.05)	(38.25, 48.88)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		7.65 (3.766)
95% C.I.		(0.25, 15.06)
p-value		0.043
Corrected Hedge’s g (SE) [1]		0.29 (0.146)
95% C.I.		(0.01, 0.58)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	98	91
LS Mean (SE)	86.13 (2.201)	90.78 (2.280)
95% C.I.	(81.80, 90.45)	(86.30, 95.26)
LS Mean Change from Baseline (SE)	19.47 (2.201)	24.12 (2.280)
95% C.I.	(15.14, 23.80)	(19.64, 28.60)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.65 (3.172)
95% C.I.		(-1.58, 10.89)
p-value		0.143
Corrected Hedge’s g (SE) [1]		0.21 (0.146)
95% C.I.		(-0.07, 0.50)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Mental Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	98	91
LS Mean (SE)	76.15 (2.141)	81.08 (2.215)
95% C.I.	(71.94, 80.36)	(76.73, 85.43)
LS Mean Change from Baseline (SE)	17.57 (2.141)	22.50 (2.215)
95% C.I.	(13.36, 21.78)	(18.15, 26.86)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.93 (3.081)
95% C.I.		(-1.12, 10.99)
p-value		0.110
Corrected Hedge’s g (SE) [1]		0.23 (0.146)
95% C.I.		(-0.05, 0.52)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Physical Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	98	91
LS Mean (SE)	51.50 (0.709)	52.58 (0.737)
95% C.I.	(50.11, 52.90)	(51.13, 54.03)
LS Mean Change from Baseline (SE)	7.49 (0.709)	8.57 (0.737)
95% C.I.	(6.10, 8.89)	(7.12, 10.02)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		1.08 (1.026)
95% C.I.		(-0.94, 3.09)
p-value		0.294
Corrected Hedge’s g (SE) [1]		0.15 (0.146)
95% C.I.		(-0.13, 0.44)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Mental Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	98	91
LS Mean (SE)	52.31 (0.921)	55.31 (0.954)
95% C.I.	(50.50, 54.12)	(53.43, 57.18)
LS Mean Change from Baseline (SE)	9.54 (0.921)	12.54 (0.954)
95% C.I.	(7.73, 11.35)	(10.66, 14.41)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.00 (1.326)
95% C.I.		(0.39, 5.60)
p-value		0.024
Corrected Hedge’s g (SE) [1]		0.33 (0.147)
95% C.I.		(0.04, 0.62)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Health Utility Index

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	98	91
LS Mean (SE)	0.81 (0.015)	0.87 (0.015)
95% C.I.	(0.78, 0.84)	(0.84, 0.90)
LS Mean Change from Baseline (SE)	0.17 (0.015)	0.23 (0.015)
95% C.I.	(0.14, 0.20)	(0.20, 0.26)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.06 (0.021)
95% C.I.		(0.02, 0.10)
p-value		0.005
Corrected Hedge’s g (SE) [1]		0.41 (0.147)
95% C.I.		(0.12, 0.70)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	98	91
LS Mean (SE)	80.10 (2.282)	85.79 (2.368)
95% C.I.	(75.61, 84.59)	(81.14, 90.45)
LS Mean Change from Baseline (SE)	31.10 (2.282)	36.80 (2.368)
95% C.I.	(26.62, 35.59)	(32.14, 41.45)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		5.69 (3.295)
95% C.I.		(-0.78, 12.17)
p-value		0.085
Corrected Hedge’s g (SE) [1]		0.25 (0.146)
95% C.I.		(-0.04, 0.54)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Male
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	98	91
LS Mean (SE)	70.23 (2.339)	77.65 (2.427)
95% C.I.	(65.63, 74.83)	(72.87, 82.42)
LS Mean Change from Baseline (SE)	30.27 (2.339)	37.68 (2.427)
95% C.I.	(25.67, 34.87)	(32.91, 42.45)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		7.42 (3.371)
95% C.I.		(0.79, 14.04)
p-value		0.028
Corrected Hedge’s g (SE) [1]		0.32 (0.147)
95% C.I.		(0.03, 0.61)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	273	299
n	117	118
LS Mean (SE)	79.02 (2.474)	77.40 (2.463)
95% C.I.	(74.16, 83.89)	(72.56, 82.24)
LS Mean Change from Baseline (SE)	19.92 (2.474)	18.30 (2.463)
95% C.I.	(15.05, 24.78)	(13.45, 23.14)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-1.62 (3.490)
95% C.I.		(-8.48, 5.24)
p-value		0.643
Corrected Hedge’s g (SE) [1]		-0.06 (0.130)
95% C.I.		(-0.32, 0.20)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Role Physical (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	117	118
LS Mean (SE)	77.29 (2.246)	77.17 (2.233)
95% C.I.	(72.88, 81.70)	(72.78, 81.56)
LS Mean Change from Baseline (SE)	25.96 (2.246)	25.84 (2.233)
95% C.I.	(21.55, 30.38)	(21.45, 30.23)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.12 (3.170)
95% C.I.		(-6.35, 6.11)
p-value		0.969
Corrected Hedge’s g (SE) [1]		0.00 (0.130)
95% C.I.		(-0.26, 0.25)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	117	118
LS Mean (SE)	85.62 (1.960)	86.42 (1.953)
95% C.I.	(81.77, 89.48)	(82.58, 90.26)
LS Mean Change from Baseline (SE)	23.36 (1.960)	24.16 (1.953)
95% C.I.	(19.51, 27.21)	(20.32, 28.00)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.80 (2.766)
95% C.I.		(-4.64, 6.24)
p-value		0.773
Corrected Hedge’s g (SE) [1]		0.04 (0.130)
95% C.I.		(-0.22, 0.29)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: General Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	117	118
LS Mean (SE)	71.10 (1.806)	65.64 (1.798)
95% C.I.	(67.55, 74.65)	(62.11, 69.18)
LS Mean Change from Baseline (SE)	14.66 (1.806)	9.21 (1.798)
95% C.I.	(11.11, 18.21)	(5.67, 12.74)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-5.45 (2.548)
95% C.I.		(-10.46, -0.44)
p-value		0.033
Corrected Hedge’s g (SE) [1]		-0.28 (0.131)
95% C.I.		(-0.54, -0.02)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Vitality (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	117	118
LS Mean (SE)	57.72 (2.818)	60.30 (2.806)
95% C.I.	(52.18, 63.26)	(54.79, 65.82)
LS Mean Change from Baseline (SE)	21.57 (2.818)	24.16 (2.806)
95% C.I.	(16.03, 27.11)	(18.64, 29.67)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.59 (3.977)
95% C.I.		(-5.23, 10.40)
p-value		0.516
Corrected Hedge’s g (SE) [1]		0.08 (0.131)
95% C.I.		(-0.17, 0.34)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	117	118
LS Mean (SE)	79.23 (2.389)	82.40 (2.374)
95% C.I.	(74.54, 83.93)	(77.73, 87.07)
LS Mean Change from Baseline (SE)	31.89 (2.389)	35.05 (2.374)
95% C.I.	(27.19, 36.58)	(30.39, 39.72)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.17 (3.368)
95% C.I.		(-3.45, 9.79)
p-value		0.348
Corrected Hedge’s g (SE) [1]		0.12 (0.131)
95% C.I.		(-0.13, 0.38)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	117	118
LS Mean (SE)	83.37 (2.013)	85.54 (2.002)
95% C.I.	(79.42, 87.33)	(81.61, 89.48)
LS Mean Change from Baseline (SE)	16.72 (2.013)	18.88 (2.002)
95% C.I.	(12.76, 20.68)	(14.95, 22.82)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.17 (2.841)
95% C.I.		(-3.42, 7.75)
p-value		0.446
Corrected Hedge’s g (SE) [1]		0.10 (0.131)
95% C.I.		(-0.16, 0.36)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Mental Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	117	118
LS Mean (SE)	74.08 (1.957)	77.79 (1.945)
95% C.I.	(70.23, 77.93)	(73.97, 81.62)
LS Mean Change from Baseline (SE)	15.50 (1.957)	19.21 (1.945)
95% C.I.	(11.65, 19.35)	(15.39, 23.04)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.71 (2.759)
95% C.I.		(-1.71, 9.14)
p-value		0.179
Corrected Hedge’s g (SE) [1]		0.17 (0.131)
95% C.I.		(-0.08, 0.43)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Physical Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	117	118
LS Mean (SE)	51.11 (0.648)	49.91 (0.645)
95% C.I.	(49.83, 52.38)	(48.65, 51.18)
LS Mean Change from Baseline (SE)	7.10 (0.648)	5.91 (0.645)
95% C.I.	(5.83, 8.37)	(4.64, 7.17)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-1.19 (0.914)
95% C.I.		(-2.99, 0.60)
p-value		0.193
Corrected Hedge’s g (SE) [1]		-0.17 (0.131)
95% C.I.		(-0.43, 0.09)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Mental Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	117	118
LS Mean (SE)	50.91 (0.844)	52.74 (0.838)
95% C.I.	(49.25, 52.57)	(51.09, 54.38)
LS Mean Change from Baseline (SE)	8.14 (0.844)	9.96 (0.838)
95% C.I.	(6.48, 9.80)	(8.32, 11.61)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		1.82 (1.189)
95% C.I.		(-0.51, 4.16)
p-value		0.126
Corrected Hedge’s g (SE) [1]		0.20 (0.131)
95% C.I.		(-0.06, 0.46)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Health Utility Index

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	117	118
LS Mean (SE)	0.79 (0.013)	0.81 (0.013)
95% C.I.	(0.76, 0.81)	(0.78, 0.83)
LS Mean Change from Baseline (SE)	0.14 (0.013)	0.16 (0.013)
95% C.I.	(0.12, 0.17)	(0.14, 0.19)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.02 (0.019)
95% C.I.		(-0.02, 0.06)
p-value		0.274
Corrected Hedge’s g (SE) [1]		0.14 (0.131)
95% C.I.		(-0.11, 0.40)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	117	118
LS Mean (SE)	78.08 (2.086)	79.36 (2.077)
95% C.I.	(73.98, 82.18)	(75.27, 83.44)
LS Mean Change from Baseline (SE)	29.08 (2.086)	30.36 (2.077)
95% C.I.	(24.98, 33.18)	(26.28, 34.44)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		1.28 (2.945)
95% C.I.		(-4.51, 7.06)
p-value		0.665
Corrected Hedge’s g (SE) [1]		0.06 (0.130)
95% C.I.		(-0.20, 0.31)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.45
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Gender

Gender: Female
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	117	118
LS Mean (SE)	65.66 (2.141)	67.91 (2.131)
95% C.I.	(61.45, 69.87)	(63.72, 72.10)
LS Mean Change from Baseline (SE)	25.70 (2.141)	27.95 (2.131)
95% C.I.	(21.49, 29.90)	(23.76, 32.14)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.26 (3.021)
95% C.I.		(-3.68, 8.19)
p-value		0.456
Corrected Hedge’s g (SE) [1]		0.10 (0.131)
95% C.I.		(-0.16, 0.35)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.46
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Gender - GBA Approach

Gender: Male
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	256	229
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	41 (16%)	56 (24%)
Non-responder	57 (22%)	35 (15%)
Missing [1]	158 (62%)	138 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.59
95% C.I.		(0.38, 0.92)
p-value		0.022
Inverse Relative Risk [3]		0.65
95% C.I.		(0.46, 0.94)
p-value		0.022
Risk Difference (%) [4]		-8.44
95% C.I.		(-15.59, -1.28)
p-value		0.023

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.46
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Gender - GBA Approach

Gender: Female
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	273	299
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	51 (19%)	56 (19%)
Non-responder	66 (24%)	62 (21%)
Missing [1]	156 (57%)	181 (61%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.00
95% C.I.		(0.65, 1.52)
p-value		0.989
Inverse Relative Risk [3]		1.00
95% C.I.		(0.71, 1.40)
p-value		0.989
Risk Difference (%) [4]		-0.05
95% C.I.		(-6.45, 6.35)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.47
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Gender - GBA Approach

Gender: Male
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	256	229
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	39 (15%)	51 (22%)
Non-responder	59 (23%)	40 (17%)
Missing [1]	158 (62%)	138 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.63
95% C.I.		(0.40, 1.00)
p-value		0.048
Inverse Relative Risk [3]		0.68
95% C.I.		(0.47, 1.00)
p-value		0.049
Risk Difference (%) [4]		-7.04
95% C.I.		(-13.99, -0.08)
p-value		0.061

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

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Table 24.47
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Gender - GBA Approach

Gender: Female
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	273	299
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	44 (16%)	45 (15%)
Non-responder	73 (27%)	73 (24%)
Missing [1]	156 (57%)	181 (61%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.08
95% C.I.		(0.69, 1.70)
p-value		0.726
Inverse Relative Risk [3]		1.07
95% C.I.		(0.73, 1.57)
p-value		0.726
Risk Difference (%) [4]		1.07
95% C.I.		(-4.89, 7.02)
p-value		0.731

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.48
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Gender - QualityMetric Approach

Gender: Male
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	256	229
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	51 (20%)	60 (26%)
Non-responder	47 (18%)	31 (14%)
Missing [1]	158 (62%)	138 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.70
95% C.I.		(0.46, 1.07)
p-value		0.102
Inverse Relative Risk [3]		0.76
95% C.I.		(0.55, 1.06)
p-value		0.102
Risk Difference (%) [4]		-6.28
95% C.I.		(-13.79, 1.23)
p-value		0.106

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.48
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Gender - QualityMetric Approach

Gender: Female
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	273	299
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	62 (23%)	67 (22%)
Non-responder	55 (20%)	51 (17%)
Missing [1]	156 (57%)	181 (61%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.02
95% C.I.		(0.69, 1.51)
p-value		0.932
Inverse Relative Risk [3]		1.01
95% C.I.		(0.75, 1.37)
p-value		0.932
Risk Difference (%) [4]		0.30
95% C.I.		(-6.56, 7.16)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.49
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Gender - QualityMetric Approach

Gender: Male
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	256	229
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	47 (18%)	59 (26%)
Non-responder	51 (20%)	32 (14%)
Missing [1]	158 (62%)	138 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.65
95% C.I.		(0.42, 1.00)
p-value		0.050
Inverse Relative Risk [3]		0.71
95% C.I.		(0.51, 1.00)
p-value		0.051
Risk Difference (%) [4]		-7.40
95% C.I.		(-14.79, -0.02)
p-value		0.062

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

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Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.49
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Gender - QualityMetric Approach

Gender: Female
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	273	299
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	57 (21%)	56 (19%)
Non-responder	60 (22%)	62 (21%)
Missing [1]	156 (57%)	181 (61%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.15
95% C.I.		(0.76, 1.73)
p-value		0.520
Inverse Relative Risk [3]		1.11
95% C.I.		(0.80, 1.55)
p-value		0.519
Risk Difference (%) [4]		2.15
95% C.I.		(-4.39, 8.69)
p-value		0.530

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, gender (male, female) and gender by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		307	293
Baseline	SF-12 Score	n	232	224
		Mean	60.28	59.82
		SD	33.689	34.122
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	146	126
		Mean	81.16	84.13
		SD	25.858	26.192
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	124	111
		Mean	16.77	22.30
		SD	37.667	38.339
		Median	0.00	25.00
		Min.	-75.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	232	224
		Mean	44.56	44.41
		SD	10.605	10.742
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	146	126
		Mean	51.13	52.06
		SD	8.140	8.245
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	124	111
		Mean	5.28	7.02
		SD	11.857	12.069
		Median	0.00	7.87
		Min.	-23.6	-31.5
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	51.57	53.52
		SD	29.366	30.381
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	146	126
		Mean	78.94	84.33
		SD	22.920	23.342
		Median	75.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	124	111
		Mean	26.21	31.76
		SD	31.575	32.368
		Median	25.00	25.00
		Min.	-50.0	-62.5
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	41.07	41.73
		SD	9.941	10.284
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	146	126
		Mean	50.33	52.16
		SD	7.757	7.900
		Median	49.00	57.46
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	124	111
		Mean	8.87	10.75
		SD	10.689	10.957
		Median	8.46	8.46
		Min.	-16.9	-21.2
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	63.85	63.73
		SD	28.792	30.845
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	146	126
		Mean	87.67	91.47
		SD	21.625	20.289
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	124	111
		Mean	24.60	27.03
		SD	30.905	31.467
		Median	25.00	25.00
		Min.	-50.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	44.69	44.64
		SD	10.387	11.127
		Median	48.71	48.71
		Min.	21.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	146	126
		Mean	53.28	54.65
		SD	7.802	7.320
		Median	57.73	57.73
		Min.	21.7	21.7
		Max.	57.7	57.7
	Change from Baseline	n	124	111
		Mean	8.87	9.75
		SD	11.150	11.353
		Median	9.02	9.02
		Min.	-18.0	-27.1
		Max.	36.1	36.1

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	232	224
		Mean	59.27	58.62
		SD	28.704	29.337
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	146	126
		Mean	75.00	72.38
		SD	18.754	18.566
		Median	85.00	60.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	124	111
		Mean	11.53	9.64
		SD	24.637	30.442
		Median	0.00	0.00
		Min.	-60.0	-100.0
		Max.	85.0	85.0

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	232	224
		Mean	47.46	47.20
		SD	11.411	11.663
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	146	126
		Mean	53.72	52.67
		SD	7.457	7.383
		Median	57.69	47.75
		Min.	33.8	23.9
		Max.	63.7	63.7
	Change from Baseline	n	124	111
		Mean	4.59	3.83
		SD	9.795	12.103
		Median	0.00	0.00
		Min.	-23.8	-39.8
		Max.	33.8	33.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	37.34	39.40
		SD	27.963	29.510
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	146	125
		Mean	59.25	66.40
		SD	31.075	31.767
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	124	111
		Mean	24.40	25.00
		SD	33.047	40.732
		Median	25.00	25.00
		Min.	-50.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	44.08	44.89
		SD	11.003	11.612
		Median	49.07	49.07
		Min.	29.4	29.4
		Max.	68.7	68.7
Day 29	SF-12 Score	n	146	125
		Mean	52.70	55.52
		SD	12.227	12.499
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	124	111
		Mean	9.60	9.84
		SD	13.004	16.027
		Median	9.84	9.84
		Min.	-19.7	-39.3
		Max.	39.3	39.3

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	45.78	45.20
		SD	37.096	36.859
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	146	126
		Mean	81.16	87.70
		SD	26.024	26.028
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	124	111
		Mean	35.69	40.09
		SD	42.072	41.325
		Median	50.00	50.00
		Min.	-75.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	37.61	37.40
		SD	13.199	13.115
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	146	126
		Mean	50.20	52.52
		SD	9.258	9.260
		Median	56.90	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	124	111
		Mean	12.70	14.26
		SD	14.968	14.703
		Median	17.79	17.79
		Min.	-26.7	-26.7
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	67.32	66.85
		SD	27.764	30.190
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	146	126
		Mean	85.87	89.68
		SD	20.775	21.452
		Median	100.00	100.00
		Min.	12.5	0.0
		Max.	100.0	100.0
	Change from Baseline	n	124	111
		Mean	16.94	21.62
		SD	28.388	31.889
		Median	12.50	12.50
		Min.	-75.0	-62.5
		Max.	87.5	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	42.69	42.50
		SD	11.545	12.554
		Median	45.89	45.89
		Min.	14.7	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	146	126
		Mean	50.41	51.99
		SD	8.638	8.920
		Median	56.28	56.28
		Min.	19.9	14.7
		Max.	56.3	56.3
	Change from Baseline	n	124	111
		Mean	7.04	8.99
		SD	11.805	13.260
		Median	5.20	5.20
		Min.	-31.2	-26.0
		Max.	36.4	41.6

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	59.85	60.10
		SD	22.187	23.775
		Median	62.50	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	146	126
		Mean	74.66	78.67
		SD	20.019	21.276
		Median	75.00	87.50
		Min.	25.0	12.5
		Max.	100.0	100.0
	Change from Baseline	n	124	111
		Mean	15.32	18.13
		SD	26.086	30.044
		Median	12.50	12.50
		Min.	-37.5	-50.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	45.78	45.90
		SD	10.182	10.911
		Median	47.00	41.26
		Min.	18.3	18.3
		Max.	64.2	64.2
Day 29	SF-12 Score	n	146	126
		Mean	52.58	54.42
		SD	9.187	9.764
		Median	52.74	58.47
		Min.	29.8	24.1
		Max.	64.2	64.2
	Change from Baseline	n	124	111
		Mean	7.03	8.32
		SD	11.972	13.788
		Median	5.73	5.74
		Min.	-17.2	-23.0
		Max.	34.4	45.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	44.46	44.62
		SD	9.266	9.208
		Median	44.39	44.56
		Min.	18.0	20.4
		Max.	62.6	64.6
Day 29	SF-12 Score	n	146	126
		Mean	51.99	52.55
		SD	7.026	7.002
		Median	53.65	53.65
		Min.	25.0	23.6
		Max.	65.3	69.4
	Change from Baseline	n	124	111
		Mean	6.59	7.42
		SD	8.931	9.095
		Median	5.09	6.89
		Min.	-12.9	-19.7
		Max.	31.0	30.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	42.98	43.03
		SD	9.981	10.286
		Median	42.53	41.97
		Min.	13.8	14.5
		Max.	70.0	64.3
Day 29	SF-12 Score	n	146	126
		Mean	51.44	53.72
		SD	8.707	8.762
		Median	52.47	55.39
		Min.	18.3	20.4
		Max.	65.0	65.0
	Change from Baseline	n	124	111
		Mean	8.90	10.14
		SD	11.009	11.983
		Median	7.19	9.93
		Min.	-18.4	-16.6
		Max.	45.3	43.7

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	0.649	0.647
		SD	0.1224	0.1339
		Median	0.630	0.630
		Min.	0.37	0.35
		Max.	1.00	1.00
Day 29	SF-12 Score	n	146	125
		Mean	0.791	0.846
		SD	0.1381	0.1422
		Median	0.797	0.871
		Min.	0.47	0.48
		Max.	1.00	1.00
	Change from Baseline	n	124	111
		Mean	0.150	0.194
		SD	0.1578	0.1867
		Median	0.119	0.202
		Min.	-0.26	-0.31
		Max.	0.52	0.66

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	49.05	50.42
		SD	27.620	29.571
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	146	126
		Mean	80.22	85.37
		SD	22.349	22.251
		Median	87.50	100.00
		Min.	12.5	6.3
		Max.	100.0	100.0
	Change from Baseline	n	124	111
		Mean	30.39	35.30
		SD	29.492	31.910
		Median	31.25	37.50
		Min.	-56.3	-56.3
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	38.85	39.34
		SD	9.923	10.625
		Median	39.19	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 29	SF-12 Score	n	146	126
		Mean	50.05	51.90
		SD	8.031	7.996
		Median	52.66	57.16
		Min.	25.7	23.5
		Max.	57.2	57.2
	Change from Baseline	n	124	111
		Mean	10.92	12.69
		SD	10.596	11.465
		Median	11.22	13.48
		Min.	-20.2	-20.2
		Max.	35.9	35.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	41.69	43.02
		SD	24.806	25.783
		Median	43.75	43.75
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	146	126
		Mean	66.05	73.63
		SD	23.659	23.603
		Median	68.75	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	124	111
		Mean	26.46	30.74
		SD	26.506	28.531
		Median	25.00	31.25
		Min.	-50.0	-43.8
		Max.	93.8	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	231	224
		Mean	42.71	43.34
		SD	11.792	12.256
		Median	43.69	43.69
		Min.	22.9	22.9
		Max.	70.4	70.4
Day 29	SF-12 Score	n	146	126
		Mean	54.29	57.89
		SD	11.244	11.218
		Median	55.57	58.54
		Min.	22.9	22.9
		Max.	70.4	70.4
	Change from Baseline	n	124	111
		Mean	12.58	14.61
		SD	12.598	13.561
		Median	11.89	14.86
		Min.	-23.8	-20.8
		Max.	44.6	47.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		153	178
Baseline	SF-12 Score	n	114	134
		Mean	55.62	55.78
		SD	32.666	31.847
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	73	92
		Mean	80.82	78.80
		SD	24.481	29.866
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	63	81
		Mean	23.55	25.00
		SD	30.979	38.324
		Median	25.00	25.00
		Min.	-50.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	43.09	43.14
		SD	10.283	10.025
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	73	92
		Mean	51.02	50.39
		SD	7.707	9.402
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	63	81
		Mean	7.41	7.87
		SD	9.752	12.064
		Median	7.87	7.87
		Min.	-15.7	-23.6
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	50.99	50.75
		SD	25.446	27.324
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	73	92
		Mean	78.08	76.77
		SD	25.582	27.335
		Median	75.00	87.50
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	63	81
		Mean	29.17	25.93
		SD	27.496	34.617
		Median	25.00	25.00
		Min.	-50.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	40.87	40.79
		SD	8.615	9.250
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	73	92
		Mean	50.04	49.60
		SD	8.659	9.253
		Median	49.00	53.23
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	63	81
		Mean	9.87	8.78
		SD	9.307	11.719
		Median	8.46	8.46
		Min.	-16.9	-16.9
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	113	134
		Mean	62.61	58.21
		SD	28.568	28.393
		Median	75.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	73	92
		Mean	83.22	86.96
		SD	22.459	21.444
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	63	81
		Mean	19.84	30.25
		SD	26.243	31.553
		Median	25.00	25.00
		Min.	-50.0	-50.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	113	134
		Mean	44.24	42.65
		SD	10.306	10.243
		Median	48.71	39.69
		Min.	21.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	73	92
		Mean	51.68	53.02
		SD	8.103	7.737
		Median	57.73	57.73
		Min.	21.7	21.7
		Max.	57.7	57.7
	Change from Baseline	n	63	81
		Mean	7.16	10.91
		SD	9.468	11.383
		Median	9.02	9.02
		Min.	-18.0	-18.0
		Max.	27.1	36.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	53.29	47.35
		SD	27.849	28.547
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	73	92
		Mean	65.89	66.09
		SD	22.490	20.963
		Median	60.00	60.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	63	81
		Mean	15.79	19.01
		SD	25.999	32.600
		Median	0.00	0.00
		Min.	-35.0	-60.0
		Max.	85.0	85.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	45.08	42.72
		SD	11.071	11.348
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	73	92
		Mean	50.09	50.17
		SD	8.942	8.335
		Median	47.75	47.75
		Min.	33.8	23.9
		Max.	63.7	63.7
	Change from Baseline	n	63	81
		Mean	6.28	7.56
		SD	10.336	12.959
		Median	0.00	0.00
		Min.	-13.9	-23.9
		Max.	33.8	33.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	37.06	31.53
		SD	28.848	24.703
		Median	25.00	25.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	73	92
		Mean	59.59	66.85
		SD	33.237	32.964
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	63	81
		Mean	26.98	33.64
		SD	31.846	39.163
		Median	25.00	50.00
		Min.	-50.0	-100.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	43.98	41.80
		SD	11.352	9.721
		Median	39.23	39.23
		Min.	29.4	29.4
		Max.	68.7	68.7
Day 29	SF-12 Score	n	73	92
		Mean	52.84	55.70
		SD	13.078	12.971
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	63	81
		Mean	10.62	13.24
		SD	12.531	15.410
		Median	9.84	19.67
		Min.	-19.7	-39.3
		Max.	29.5	39.3

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	50.22	48.51
		SD	34.961	36.113
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	73	92
		Mean	79.79	85.33
		SD	28.461	23.776
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	63	81
		Mean	29.37	40.43
		SD	35.792	40.033
		Median	25.00	50.00
		Min.	-25.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	39.19	38.58
		SD	12.439	12.849
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	73	92
		Mean	49.71	51.68
		SD	10.125	8.458
		Median	56.90	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	63	81
		Mean	10.45	14.39
		SD	12.734	14.243
		Median	8.90	17.79
		Min.	-8.9	-26.7
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	63.49	64.93
		SD	28.180	28.243
		Median	50.00	62.50
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	73	92
		Mean	82.36	86.96
		SD	25.586	22.915
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	63	81
		Mean	19.05	22.22
		SD	26.072	31.187
		Median	12.50	25.00
		Min.	-25.0	-50.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	41.10	41.70
		SD	11.718	11.744
		Median	35.49	40.69
		Min.	14.7	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	73	92
		Mean	48.95	50.86
		SD	10.639	9.528
		Median	56.28	56.28
		Min.	14.7	14.7
		Max.	56.3	56.3
	Change from Baseline	n	63	81
		Mean	7.92	9.24
		SD	10.841	12.968
		Median	5.20	10.39
		Min.	-10.4	-20.8
		Max.	31.2	41.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	58.55	57.56
		SD	24.060	23.698
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	73	92
		Mean	73.12	78.40
		SD	24.971	21.218
		Median	75.00	87.50
		Min.	12.5	25.0
		Max.	100.0	100.0
	Change from Baseline	n	63	81
		Mean	13.89	24.23
		SD	24.502	29.205
		Median	12.50	25.00
		Min.	-37.5	-50.0
		Max.	62.5	87.5

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	45.19	44.73
		SD	11.041	10.875
		Median	41.26	41.26
		Min.	18.3	18.3
		Max.	64.2	64.2
Day 29	SF-12 Score	n	73	92
		Mean	51.87	54.29
		SD	11.460	9.738
		Median	52.74	58.47
		Min.	24.1	29.8
		Max.	64.2	64.2
	Change from Baseline	n	63	81
		Mean	6.37	11.12
		SD	11.246	13.402
		Median	5.73	11.47
		Min.	-17.2	-23.0
		Max.	28.7	40.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	43.53	42.32
		SD	8.746	8.352
		Median	43.92	41.53
		Min.	17.4	20.2
		Max.	61.3	62.1
Day 29	SF-12 Score	n	73	92
		Mean	50.88	50.06
		SD	6.886	8.289
		Median	51.32	53.06
		Min.	29.7	26.1
		Max.	63.4	61.5
	Change from Baseline	n	63	81
		Mean	7.75	7.81
		SD	8.112	10.113
		Median	7.42	8.34
		Min.	-11.5	-15.0
		Max.	35.6	28.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	42.82	42.38
		SD	10.741	10.387
		Median	41.18	41.61
		Min.	17.7	11.0
		Max.	73.0	65.4
Day 29	SF-12 Score	n	73	92
		Mean	50.64	53.91
		SD	11.636	8.934
		Median	53.23	56.91
		Min.	16.0	29.0
		Max.	65.6	66.8
	Change from Baseline	n	63	81
		Mean	8.12	12.32
		SD	11.193	13.036
		Median	6.10	12.87
		Min.	-12.9	-20.6
		Max.	32.7	41.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	113	134
		Mean	0.652	0.636
		SD	0.1290	0.1227
		Median	0.615	0.615
		Min.	0.35	0.35
		Max.	1.00	0.92
Day 29	SF-12 Score	n	73	92
		Mean	0.795	0.832
		SD	0.1602	0.1511
		Median	0.782	0.859
		Min.	0.41	0.48
		Max.	1.00	1.00
	Change from Baseline	n	63	81
		Mean	0.140	0.204
		SD	0.1590	0.1850
		Median	0.116	0.229
		Min.	-0.13	-0.29
		Max.	0.45	0.63

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	50.71	47.57
		SD	25.121	26.360
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	73	92
		Mean	77.14	79.48
		SD	24.456	24.799
		Median	81.25	87.50
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	63	81
		Mean	28.57	32.72
		SD	25.787	31.082
		Median	25.00	37.50
		Min.	-25.0	-37.5
		Max.	87.5	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	39.45	38.32
		SD	9.025	9.470
		Median	39.19	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 29	SF-12 Score	n	73	92
		Mean	48.94	49.79
		SD	8.788	8.911
		Median	50.42	52.66
		Min.	21.2	21.2
		Max.	57.2	57.2
	Change from Baseline	n	63	81
		Mean	10.27	11.76
		SD	9.265	11.168
		Median	8.98	13.47
		Min.	-9.0	-13.5
		Max.	31.4	35.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	42.32	36.85
		SD	24.314	22.296
		Median	43.75	43.75
		Min.	0.0	0.0
		Max.	100.0	93.8
Day 29	SF-12 Score	n	73	92
		Mean	67.89	71.74
		SD	27.976	25.247
		Median	68.75	71.88
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	63	81
		Mean	29.17	34.95
		SD	25.126	30.695
		Median	25.00	37.50
		Min.	-18.8	-50.0
		Max.	81.3	93.8

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	114	134
		Mean	43.01	40.41
		SD	11.558	10.599
		Median	43.69	43.69
		Min.	22.9	22.9
		Max.	70.4	67.5
Day 29	SF-12 Score	n	73	92
		Mean	55.16	56.99
		SD	13.297	11.999
		Median	55.57	57.06
		Min.	22.9	22.9
		Max.	70.4	70.4
	Change from Baseline	n	63	81
		Mean	13.86	16.61
		SD	11.942	14.590
		Median	11.89	17.83
		Min.	-8.9	-23.8
		Max.	38.6	44.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		69	57
Baseline	SF-12 Score	n	53	41
		Mean	40.09	48.17
		SD	30.358	30.817
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	38	23
		Mean	68.42	71.74
		SD	33.229	37.161
		Median	75.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	28	17
		Mean	25.00	22.06
		SD	38.490	34.098
		Median	25.00	25.00
		Min.	-50.0	-50.0
		Max.	100.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	38.20	40.74
		SD	9.557	9.701
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	38	23
		Mean	47.12	48.16
		SD	10.461	11.698
		Median	49.19	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	28	17
		Mean	7.87	6.94
		SD	12.117	10.734
		Median	7.87	7.87
		Min.	-15.7	-15.7
		Max.	31.5	23.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	44.34	52.74
		SD	22.940	22.966
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	38	23
		Mean	65.46	75.00
		SD	27.941	29.436
		Median	62.50	87.50
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	28	17
		Mean	22.32	24.26
		SD	31.061	23.992
		Median	12.50	25.00
		Min.	-25.0	-25.0
		Max.	87.5	62.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	38.62	41.47
		SD	7.767	7.775
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	38	23
		Mean	45.77	49.00
		SD	9.458	9.964
		Median	44.77	53.23
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	28	17
		Mean	7.55	8.21
		SD	10.514	8.119
		Median	4.23	8.46
		Min.	-8.5	-8.5
		Max.	29.6	21.2

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	54.25	53.05
		SD	32.052	29.683
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	38	23
		Mean	82.89	80.43
		SD	26.702	27.132
		Median	100.00	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	28	17
		Mean	25.89	17.65
		SD	35.015	29.000
		Median	25.00	25.00
		Min.	-50.0	-25.0
		Max.	100.0	50.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	41.22	40.79
		SD	11.563	10.708
		Median	39.69	39.69
		Min.	21.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	38	23
		Mean	51.56	50.67
		SD	9.633	9.789
		Median	57.73	57.73
		Min.	21.7	30.7
		Max.	57.7	57.7
	Change from Baseline	n	28	17
		Mean	9.34	6.37
		SD	12.632	10.462
		Median	9.02	9.02
		Min.	-18.0	-9.0
		Max.	36.1	18.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	46.23	50.37
		SD	24.805	27.166
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	85.0	100.0
Day 29	SF-12 Score	n	38	23
		Mean	64.61	58.48
		SD	19.500	23.033
		Median	60.00	60.00
		Min.	0.0	25.0
		Max.	100.0	85.0
	Change from Baseline	n	28	17
		Mean	13.93	12.94
		SD	28.459	32.116
		Median	0.00	0.00
		Min.	-35.0	-35.0
		Max.	75.0	85.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	42.28	43.92
		SD	9.860	10.799
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	57.7	63.7
Day 29	SF-12 Score	n	38	23
		Mean	49.58	47.15
		SD	7.753	9.156
		Median	47.75	47.75
		Min.	23.9	33.8
		Max.	63.7	57.7
	Change from Baseline	n	28	17
		Mean	5.54	5.14
		SD	11.314	12.766
		Median	0.00	0.00
		Min.	-13.9	-13.9
		Max.	29.8	33.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	31.13	36.59
		SD	25.432	27.442
		Median	25.00	25.00
		Min.	0.0	0.0
		Max.	75.0	100.0
Day 29	SF-12 Score	n	38	23
		Mean	63.82	65.22
		SD	31.137	35.944
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	28	17
		Mean	25.00	27.94
		SD	27.217	19.530
		Median	25.00	25.00
		Min.	-50.0	0.0
		Max.	75.0	50.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	41.64	43.79
		SD	10.008	10.799
		Median	39.23	39.23
		Min.	29.4	29.4
		Max.	58.9	68.7
Day 29	SF-12 Score	n	38	23
		Mean	54.50	55.05
		SD	12.251	14.143
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	28	17
		Mean	9.84	10.99
		SD	10.709	7.683
		Median	9.84	9.84
		Min.	-19.7	0.0
		Max.	29.5	19.7

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	45.28	49.39
		SD	32.910	30.356
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	38	23
		Mean	80.92	79.35
		SD	26.274	28.853
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	28	17
		Mean	30.36	29.41
		SD	34.932	36.695
		Median	25.00	50.00
		Min.	-25.0	-50.0
		Max.	100.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	37.43	38.89
		SD	11.709	10.800
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	38	23
		Mean	50.11	49.55
		SD	9.348	10.265
		Median	56.90	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	28	17
		Mean	10.80	10.47
		SD	12.428	13.055
		Median	8.89	17.79
		Min.	-8.9	-17.8
		Max.	35.6	26.7

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	57.08	74.09
		SD	27.134	24.747
		Median	50.00	75.00
		Min.	12.5	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	38	23
		Mean	79.28	81.52
		SD	26.994	24.094
		Median	93.75	100.00
		Min.	0.0	37.5
		Max.	100.0	100.0
	Change from Baseline	n	28	17
		Mean	19.64	13.97
		SD	32.352	30.581
		Median	18.75	0.00
		Min.	-50.0	-50.0
		Max.	75.0	50.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	38.43	45.51
		SD	11.284	10.290
		Median	35.49	45.89
		Min.	19.9	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	38	23
		Mean	47.66	48.60
		SD	11.225	10.019
		Median	53.68	56.28
		Min.	14.7	30.3
		Max.	56.3	56.3
	Change from Baseline	n	28	17
		Mean	8.17	5.81
		SD	13.452	12.717
		Median	7.80	0.00
		Min.	-20.8	-20.8
		Max.	31.2	20.8

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	51.89	59.45
		SD	19.519	24.492
		Median	50.00	50.00
		Min.	12.5	12.5
		Max.	100.0	100.0
Day 29	SF-12 Score	n	38	23
		Mean	77.63	75.54
		SD	24.168	23.073
		Median	87.50	75.00
		Min.	12.5	37.5
		Max.	100.0	100.0
	Change from Baseline	n	28	17
		Mean	25.89	22.06
		SD	27.624	28.821
		Median	25.00	25.00
		Min.	-25.0	-37.5
		Max.	75.0	50.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	42.13	45.60
		SD	8.957	11.240
		Median	41.26	41.26
		Min.	24.1	24.1
		Max.	64.2	64.2
Day 29	SF-12 Score	n	38	23
		Mean	53.94	52.99
		SD	11.091	10.589
		Median	58.47	52.74
		Min.	24.1	35.5
		Max.	64.2	64.2
	Change from Baseline	n	28	17
		Mean	11.88	10.13
		SD	12.678	13.227
		Median	11.47	11.48
		Min.	-11.5	-17.2
		Max.	34.4	23.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	40.10	40.38
		SD	8.543	8.005
		Median	40.18	40.29
		Min.	21.2	25.4
		Max.	57.6	57.6
Day 29	SF-12 Score	n	38	23
		Mean	47.39	48.13
		SD	8.424	10.150
		Median	48.24	53.65
		Min.	22.7	23.5
		Max.	60.1	61.2
	Change from Baseline	n	28	17
		Mean	6.35	6.02
		SD	10.258	7.289
		Median	5.57	7.92
		Min.	-13.3	-6.0
		Max.	31.7	20.4

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	40.90	45.64
		SD	8.568	10.509
		Median	40.51	45.15
		Min.	22.4	19.6
		Max.	58.1	69.3
Day 29	SF-12 Score	n	38	23
		Mean	53.03	52.44
		SD	10.380	9.887
		Median	55.38	51.33
		Min.	28.7	30.8
		Max.	64.7	63.9
	Change from Baseline	n	28	17
		Mean	10.80	9.53
		SD	11.691	12.665
		Median	10.68	10.26
		Min.	-8.3	-12.5
		Max.	33.5	26.6

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	0.599	0.632
		SD	0.0971	0.1380
		Median	0.600	0.615
		Min.	0.42	0.43
		Max.	0.86	1.00
Day 29	SF-12 Score	n	38	23
		Mean	0.788	0.797
		SD	0.1659	0.1875
		Median	0.806	0.800
		Min.	0.42	0.43
		Max.	1.00	1.00
	Change from Baseline	n	28	17
		Mean	0.187	0.146
		SD	0.1690	0.1649
		Median	0.180	0.167
		Min.	-0.08	-0.11
		Max.	0.52	0.39

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	42.92	51.37
		SD	22.636	22.164
		Median	43.75	50.00
		Min.	0.0	6.3
		Max.	100.0	100.0
Day 29	SF-12 Score	n	38	23
		Mean	71.22	78.53
		SD	24.768	25.963
		Median	75.00	93.75
		Min.	6.3	25.0
		Max.	100.0	100.0
	Change from Baseline	n	28	17
		Mean	27.68	27.57
		SD	29.089	24.908
		Median	28.13	37.50
		Min.	-18.8	-25.0
		Max.	87.5	56.3

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	36.65	39.68
		SD	8.132	7.963
		Median	36.95	39.19
		Min.	21.2	23.5
		Max.	57.2	57.2
Day 29	SF-12 Score	n	38	23
		Mean	46.81	49.44
		SD	8.899	9.329
		Median	48.17	54.91
		Min.	23.5	30.2
		Max.	57.2	57.2
	Change from Baseline	n	28	17
		Mean	9.94	9.91
		SD	10.451	8.950
		Median	10.11	13.47
		Min.	-6.7	-9.0
		Max.	31.4	20.2

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	33.61	42.84
		SD	20.074	23.699
		Median	37.50	50.00
		Min.	0.0	0.0
		Max.	81.3	100.0
Day 29	SF-12 Score	n	38	23
		Mean	69.24	68.48
		SD	26.887	31.334
		Median	75.00	68.75
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	28	17
		Mean	31.25	27.21
		SD	23.199	19.633
		Median	25.00	25.00
		Min.	-12.5	-6.3
		Max.	75.0	62.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.55
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	53	41
		Mean	38.87	43.25
		SD	9.544	11.265
		Median	40.72	46.66
		Min.	22.9	22.9
		Max.	61.5	70.4
Day 29	SF-12 Score	n	38	23
		Mean	55.80	55.44
		SD	12.779	14.892
		Median	58.54	55.57
		Min.	22.9	22.9
		Max.	70.4	70.4
	Change from Baseline	n	28	17
		Mean	14.85	12.93
		SD	11.027	9.329
		Median	11.89	11.88
		Min.	-5.9	-3.0
		Max.	35.7	29.7

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	307	293
n	124	111
LS Mean (SE)	80.61 (2.415)	83.82 (2.543)
95% C.I.	(75.86, 85.36)	(78.82, 88.82)
LS Mean Change from Baseline (SE)	21.50 (2.415)	24.72 (2.543)
95% C.I.	(16.76, 26.25)	(19.72, 29.71)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.21 (3.498)
95% C.I.		(-3.66, 10.09)
p-value		0.359
Corrected Hedge’s g (SE) [1]		0.12 (0.131)
95% C.I.		(-0.14, 0.38)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Role Physical (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	124	111
LS Mean (SE)	78.43 (2.164)	84.54 (2.288)
95% C.I.	(74.18, 82.69)	(80.04, 89.04)
LS Mean Change from Baseline (SE)	27.11 (2.164)	33.21 (2.288)
95% C.I.	(22.85, 31.36)	(28.72, 37.71)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		6.11 (3.147)
95% C.I.		(-0.08, 12.29)
p-value		0.053
Corrected Hedge’s g (SE) [1]		0.25 (0.131)
95% C.I.		(0.00, 0.51)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	124	111
LS Mean (SE)	88.15 (1.903)	90.79 (2.011)
95% C.I.	(84.41, 91.89)	(86.84, 94.75)
LS Mean Change from Baseline (SE)	25.88 (1.903)	28.53 (2.011)
95% C.I.	(22.14, 29.62)	(24.58, 32.48)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.65 (2.767)
95% C.I.		(-2.79, 8.09)
p-value		0.339
Corrected Hedge’s g (SE) [1]		0.12 (0.131)
95% C.I.		(-0.13, 0.38)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: General Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	124	111
LS Mean (SE)	73.63 (1.768)	70.51 (1.860)
95% C.I.	(70.16, 77.11)	(66.85, 74.16)
LS Mean Change from Baseline (SE)	17.20 (1.768)	14.07 (1.860)
95% C.I.	(13.72, 20.67)	(10.41, 17.72)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-3.13 (2.546)
95% C.I.		(-8.13, 1.88)
p-value		0.220
Corrected Hedge’s g (SE) [1]		-0.16 (0.131)
95% C.I.		(-0.42, 0.10)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Vitality (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	124	111
LS Mean (SE)	59.48 (2.776)	64.51 (2.946)
95% C.I.	(54.02, 64.93)	(58.72, 70.30)
LS Mean Change from Baseline (SE)	23.33 (2.776)	28.37 (2.946)
95% C.I.	(17.88, 28.79)	(22.58, 34.16)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		5.03 (4.054)
95% C.I.		(-2.94, 13.00)
p-value		0.215
Corrected Hedge’s g (SE) [1]		0.16 (0.131)
95% C.I.		(-0.09, 0.42)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	124	111
LS Mean (SE)	81.34 (2.337)	87.59 (2.469)
95% C.I.	(76.75, 85.93)	(82.73, 92.44)
LS Mean Change from Baseline (SE)	33.99 (2.337)	40.24 (2.469)
95% C.I.	(29.40, 38.59)	(35.39, 45.09)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		6.25 (3.399)
95% C.I.		(-0.44, 12.93)
p-value		0.067
Corrected Hedge’s g (SE) [1]		0.24 (0.131)
95% C.I.		(-0.02, 0.50)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	124	111
LS Mean (SE)	85.61 (1.959)	89.63 (2.069)
95% C.I.	(81.76, 89.46)	(85.57, 93.70)
LS Mean Change from Baseline (SE)	18.95 (1.959)	22.98 (2.069)
95% C.I.	(15.10, 22.80)	(18.91, 27.04)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.02 (2.846)
95% C.I.		(-1.57, 9.62)
p-value		0.158
Corrected Hedge’s g (SE) [1]		0.18 (0.131)
95% C.I.		(-0.07, 0.44)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Mental Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	124	111
LS Mean (SE)	74.87 (1.904)	78.70 (2.015)
95% C.I.	(71.13, 78.62)	(74.74, 82.66)
LS Mean Change from Baseline (SE)	16.29 (1.904)	20.12 (2.015)
95% C.I.	(12.55, 20.04)	(16.16, 24.08)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.83 (2.769)
95% C.I.		(-1.62, 9.27)
p-value		0.168
Corrected Hedge’s g (SE) [1]		0.18 (0.131)
95% C.I.		(-0.08, 0.44)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Physical Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	124	111
LS Mean (SE)	51.63 (0.630)	52.17 (0.664)
95% C.I.	(50.39, 52.87)	(50.86, 53.48)
LS Mean Change from Baseline (SE)	7.62 (0.630)	8.16 (0.664)
95% C.I.	(6.38, 8.86)	(6.86, 9.47)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.54 (0.913)
95% C.I.		(-1.25, 2.34)
p-value		0.553
Corrected Hedge’s g (SE) [1]		0.08 (0.131)
95% C.I.		(-0.18, 0.33)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Mental Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	124	111
LS Mean (SE)	51.54 (0.823)	53.65 (0.871)
95% C.I.	(49.92, 53.16)	(51.94, 55.36)
LS Mean Change from Baseline (SE)	8.77 (0.823)	10.88 (0.871)
95% C.I.	(7.15, 10.39)	(9.17, 12.59)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.11 (1.198)
95% C.I.		(-0.25, 4.47)
p-value		0.079
Corrected Hedge’s g (SE) [1]		0.23 (0.131)
95% C.I.		(-0.03, 0.49)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Health Utility Index

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	124	111
LS Mean (SE)	0.80 (0.013)	0.85 (0.014)
95% C.I.	(0.77, 0.82)	(0.82, 0.87)
LS Mean Change from Baseline (SE)	0.15 (0.013)	0.20 (0.014)
95% C.I.	(0.13, 0.18)	(0.18, 0.23)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.05 (0.019)
95% C.I.		(0.01, 0.09)
p-value		0.008
Corrected Hedge’s g (SE) [1]		0.35 (0.132)
95% C.I.		(0.09, 0.61)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	124	111
LS Mean (SE)	80.09 (2.027)	85.29 (2.142)
95% C.I.	(76.11, 84.08)	(81.08, 89.50)
LS Mean Change from Baseline (SE)	31.10 (2.027)	36.29 (2.142)
95% C.I.	(27.11, 35.08)	(32.08, 40.50)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		5.20 (2.948)
95% C.I.		(-0.60, 10.99)
p-value		0.079
Corrected Hedge’s g (SE) [1]		0.23 (0.131)
95% C.I.		(-0.03, 0.49)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	124	111
LS Mean (SE)	66.43 (2.106)	72.76 (2.233)
95% C.I.	(62.29, 70.57)	(68.37, 77.15)
LS Mean Change from Baseline (SE)	26.47 (2.106)	32.80 (2.233)
95% C.I.	(22.33, 30.61)	(28.41, 37.18)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		6.33 (3.069)
95% C.I.		(0.30, 12.36)
p-value		0.040
Corrected Hedge’s g (SE) [1]		0.27 (0.131)
95% C.I.		(0.01, 0.53)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	153	178
n	63	81
LS Mean (SE)	83.51 (3.371)	78.85 (2.985)
95% C.I.	(76.88, 90.13)	(72.98, 84.72)
LS Mean Change from Baseline (SE)	24.40 (3.371)	19.75 (2.985)
95% C.I.	(17.77, 31.03)	(13.88, 25.61)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-4.66 (4.506)
95% C.I.		(-13.51, 4.20)
p-value		0.302
Corrected Hedge’s g (SE) [1]		-0.17 (0.168)
95% C.I.		(-0.50, 0.16)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Role Physical (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	63	81
LS Mean (SE)	80.54 (3.034)	75.79 (2.678)
95% C.I.	(74.58, 86.50)	(70.53, 81.05)
LS Mean Change from Baseline (SE)	29.21 (3.034)	24.47 (2.678)
95% C.I.	(23.25, 35.18)	(19.20, 29.73)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-4.75 (4.047)
95% C.I.		(-12.70, 3.21)
p-value		0.241
Corrected Hedge’s g (SE) [1]		-0.20 (0.168)
95% C.I.		(-0.53, 0.13)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	63	81
LS Mean (SE)	84.30 (2.670)	88.24 (2.361)
95% C.I.	(79.05, 89.55)	(83.60, 92.88)
LS Mean Change from Baseline (SE)	22.04 (2.670)	25.97 (2.361)
95% C.I.	(16.79, 27.29)	(21.33, 30.62)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.94 (3.570)
95% C.I.		(-3.08, 10.95)
p-value		0.271
Corrected Hedge’s g (SE) [1]		0.18 (0.168)
95% C.I.		(-0.15, 0.51)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: General Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	63	81
LS Mean (SE)	68.58 (2.459)	67.43 (2.195)
95% C.I.	(63.75, 73.41)	(63.12, 71.74)
LS Mean Change from Baseline (SE)	12.14 (2.459)	10.99 (2.195)
95% C.I.	(7.31, 16.98)	(6.68, 15.30)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-1.15 (3.278)
95% C.I.		(-7.59, 5.29)
p-value		0.726
Corrected Hedge’s g (SE) [1]		-0.06 (0.168)
95% C.I.		(-0.39, 0.27)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Vitality (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	63	81
LS Mean (SE)	62.35 (3.892)	67.21 (3.439)
95% C.I.	(54.70, 70.00)	(60.45, 73.97)
LS Mean Change from Baseline (SE)	26.21 (3.892)	31.07 (3.439)
95% C.I.	(18.56, 33.86)	(24.31, 37.83)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.86 (5.191)
95% C.I.		(-5.34, 15.07)
p-value		0.349
Corrected Hedge’s g (SE) [1]		0.16 (0.168)
95% C.I.		(-0.17, 0.49)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	63	81
LS Mean (SE)	80.33 (3.280)	85.57 (2.891)
95% C.I.	(73.88, 86.78)	(79.88, 91.25)
LS Mean Change from Baseline (SE)	32.98 (3.280)	38.22 (2.891)
95% C.I.	(26.53, 39.43)	(32.54, 43.90)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		5.24 (4.376)
95% C.I.		(-3.37, 13.84)
p-value		0.232
Corrected Hedge’s g (SE) [1]		0.20 (0.168)
95% C.I.		(-0.13, 0.53)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	63	81
LS Mean (SE)	83.48 (2.747)	87.15 (2.422)
95% C.I.	(78.09, 88.88)	(82.39, 91.91)
LS Mean Change from Baseline (SE)	16.83 (2.747)	20.50 (2.422)
95% C.I.	(11.43, 22.23)	(15.74, 25.26)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.67 (3.659)
95% C.I.		(-3.52, 10.86)
p-value		0.317
Corrected Hedge’s g (SE) [1]		0.17 (0.168)
95% C.I.		(-0.16, 0.50)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Mental Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	63	81
LS Mean (SE)	73.56 (2.670)	79.98 (2.360)
95% C.I.	(68.31, 78.80)	(75.34, 84.62)
LS Mean Change from Baseline (SE)	14.98 (2.670)	21.40 (2.360)
95% C.I.	(9.73, 20.23)	(16.76, 26.04)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		6.43 (3.567)
95% C.I.		(-0.58, 13.44)
p-value		0.072
Corrected Hedge’s g (SE) [1]		0.30 (0.169)
95% C.I.		(-0.03, 0.63)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Physical Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	63	81
LS Mean (SE)	51.83 (0.880)	50.27 (0.781)
95% C.I.	(50.10, 53.56)	(48.73, 51.80)
LS Mean Change from Baseline (SE)	7.82 (0.880)	6.26 (0.781)
95% C.I.	(6.09, 9.55)	(4.72, 7.79)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-1.56 (1.177)
95% C.I.		(-3.87, 0.75)
p-value		0.186
Corrected Hedge’s g (SE) [1]		-0.22 (0.168)
95% C.I.		(-0.55, 0.11)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Mental Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	63	81
LS Mean (SE)	50.82 (1.154)	54.34 (1.019)
95% C.I.	(48.56, 53.09)	(52.34, 56.34)
LS Mean Change from Baseline (SE)	8.05 (1.154)	11.57 (1.019)
95% C.I.	(5.78, 10.32)	(9.57, 13.57)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.52 (1.540)
95% C.I.		(0.49, 6.54)
p-value		0.023
Corrected Hedge’s g (SE) [1]		0.38 (0.169)
95% C.I.		(0.05, 0.71)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Health Utility Index

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	63	81
LS Mean (SE)	0.80 (0.018)	0.83 (0.016)
95% C.I.	(0.76, 0.84)	(0.80, 0.86)
LS Mean Change from Baseline (SE)	0.16 (0.018)	0.19 (0.016)
95% C.I.	(0.12, 0.19)	(0.16, 0.22)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.03 (0.025)
95% C.I.		(-0.02, 0.08)
p-value		0.186
Corrected Hedge’s g (SE) [1]		0.22 (0.168)
95% C.I.		(-0.11, 0.55)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	63	81
LS Mean (SE)	78.60 (2.843)	79.26 (2.511)
95% C.I.	(73.01, 84.19)	(74.33, 84.20)
LS Mean Change from Baseline (SE)	29.60 (2.843)	30.27 (2.511)
95% C.I.	(24.01, 35.19)	(25.33, 35.20)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.66 (3.796)
95% C.I.		(-6.80, 8.12)
p-value		0.861
Corrected Hedge’s g (SE) [1]		0.03 (0.168)
95% C.I.		(-0.30, 0.36)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	63	81
LS Mean (SE)	69.73 (2.955)	72.58 (2.613)
95% C.I.	(63.92, 75.54)	(67.44, 77.72)
LS Mean Change from Baseline (SE)	29.77 (2.955)	32.62 (2.613)
95% C.I.	(23.96, 35.58)	(27.48, 37.75)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.85 (3.947)
95% C.I.		(-4.91, 10.61)
p-value		0.471
Corrected Hedge’s g (SE) [1]		0.12 (0.168)
95% C.I.		(-0.21, 0.45)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	69	57
n	28	17
LS Mean (SE)	73.36 (5.086)	70.46 (6.512)
95% C.I.	(63.37, 83.36)	(57.66, 83.27)
LS Mean Change from Baseline (SE)	14.26 (5.086)	11.36 (6.512)
95% C.I.	(4.26, 24.26)	(-1.44, 24.16)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.90 (8.227)
95% C.I.		(-19.07, 13.27)
p-value		0.725
Corrected Hedge’s g (SE) [1]		-0.11 (0.308)
95% C.I.		(-0.71, 0.50)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Role Physical (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	28	17
LS Mean (SE)	70.64 (4.555)	71.28 (5.847)
95% C.I.	(61.68, 79.59)	(59.79, 82.77)
LS Mean Change from Baseline (SE)	19.31 (4.555)	19.95 (5.847)
95% C.I.	(10.36, 28.27)	(8.46, 31.45)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.64 (7.406)
95% C.I.		(-13.92, 15.20)
p-value		0.931
Corrected Hedge’s g (SE) [1]		0.03 (0.307)
95% C.I.		(-0.58, 0.63)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	28	17
LS Mean (SE)	84.86 (4.005)	78.37 (5.137)
95% C.I.	(76.98, 92.73)	(68.28, 88.47)
LS Mean Change from Baseline (SE)	22.59 (4.005)	16.11 (5.137)
95% C.I.	(14.72, 30.47)	(6.01, 26.21)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-6.48 (6.512)
95% C.I.		(-19.28, 6.32)
p-value		0.320
Corrected Hedge’s g (SE) [1]		-0.30 (0.309)
95% C.I.		(-0.91, 0.31)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: General Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	28	17
LS Mean (SE)	64.89 (3.689)	59.93 (4.743)
95% C.I.	(57.64, 72.14)	(50.60, 69.25)
LS Mean Change from Baseline (SE)	8.45 (3.689)	3.49 (4.743)
95% C.I.	(1.20, 15.70)	(-5.84, 12.81)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-4.96 (5.991)
95% C.I.		(-16.74, 6.81)
p-value		0.408
Corrected Hedge’s g (SE) [1]		-0.25 (0.309)
95% C.I.		(-0.85, 0.36)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Vitality (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	28	17
LS Mean (SE)	62.01 (5.838)	63.54 (7.492)
95% C.I.	(50.53, 73.48)	(48.82, 78.27)
LS Mean Change from Baseline (SE)	25.86 (5.838)	27.40 (7.492)
95% C.I.	(14.39, 37.34)	(12.67, 42.13)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		1.54 (9.499)
95% C.I.		(-17.13, 20.21)
p-value		0.871
Corrected Hedge’s g (SE) [1]		0.05 (0.308)
95% C.I.		(-0.55, 0.65)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	28	17
LS Mean (SE)	81.49 (4.918)	79.02 (6.309)
95% C.I.	(71.82, 91.16)	(66.62, 91.42)
LS Mean Change from Baseline (SE)	34.14 (4.918)	31.68 (6.309)
95% C.I.	(24.48, 43.81)	(19.27, 44.08)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.47 (7.997)
95% C.I.		(-18.19, 13.25)
p-value		0.758
Corrected Hedge’s g (SE) [1]		-0.09 (0.308)
95% C.I.		(-0.70, 0.51)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	28	17
LS Mean (SE)	82.86 (4.120)	79.17 (5.283)
95% C.I.	(74.76, 90.95)	(68.78, 89.55)
LS Mean Change from Baseline (SE)	16.20 (4.120)	12.51 (5.283)
95% C.I.	(8.10, 24.30)	(2.13, 22.90)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-3.69 (6.698)
95% C.I.		(-16.85, 9.48)
p-value		0.582
Corrected Hedge’s g (SE) [1]		-0.17 (0.308)
95% C.I.		(-0.77, 0.44)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Mental Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	28	17
LS Mean (SE)	78.97 (4.017)	79.05 (5.140)
95% C.I.	(71.07, 86.86)	(68.94, 89.15)
LS Mean Change from Baseline (SE)	20.39 (4.017)	20.47 (5.140)
95% C.I.	(12.49, 28.28)	(10.37, 30.57)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.08 (6.519)
95% C.I.		(-12.73, 12.90)
p-value		0.990
Corrected Hedge’s g (SE) [1]		0.00 (0.307)
95% C.I.		(-0.60, 0.61)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Physical Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	28	17
LS Mean (SE)	48.70 (1.324)	47.57 (1.700)
95% C.I.	(46.09, 51.30)	(44.22, 50.91)
LS Mean Change from Baseline (SE)	4.69 (1.324)	3.56 (1.700)
95% C.I.	(2.09, 7.29)	(0.22, 6.90)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-1.13 (2.148)
95% C.I.		(-5.35, 3.09)
p-value		0.600
Corrected Hedge’s g (SE) [1]		-0.16 (0.308)
95% C.I.		(-0.76, 0.45)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Mental Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	28	17
LS Mean (SE)	53.23 (1.731)	52.86 (2.222)
95% C.I.	(49.83, 56.63)	(48.49, 57.23)
LS Mean Change from Baseline (SE)	10.46 (1.731)	10.09 (2.222)
95% C.I.	(7.05, 13.86)	(5.72, 14.46)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.37 (2.817)
95% C.I.		(-5.91, 5.17)
p-value		0.896
Corrected Hedge’s g (SE) [1]		-0.04 (0.307)
95% C.I.		(-0.64, 0.56)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Health Utility Index

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	28	17
LS Mean (SE)	0.81 (0.028)	0.78 (0.035)
95% C.I.	(0.75, 0.86)	(0.71, 0.85)
LS Mean Change from Baseline (SE)	0.16 (0.028)	0.13 (0.035)
95% C.I.	(0.11, 0.22)	(0.07, 0.20)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.03 (0.045)
95% C.I.		(-0.12, 0.06)
p-value		0.512
Corrected Hedge’s g (SE) [1]		-0.20 (0.308)
95% C.I.		(-0.80, 0.41)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	28	17
LS Mean (SE)	75.11 (4.265)	75.41 (5.473)
95% C.I.	(66.73, 83.49)	(64.65, 86.17)
LS Mean Change from Baseline (SE)	26.11 (4.265)	26.41 (5.473)
95% C.I.	(17.73, 34.50)	(15.66, 37.17)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.30 (6.938)
95% C.I.		(-13.34, 13.94)
p-value		0.965
Corrected Hedge’s g (SE) [1]		0.01 (0.307)
95% C.I.		(-0.59, 0.62)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.56
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	28	17
LS Mean (SE)	69.08 (4.436)	66.14 (5.689)
95% C.I.	(60.36, 77.80)	(54.96, 77.32)
LS Mean Change from Baseline (SE)	29.12 (4.436)	26.18 (5.689)
95% C.I.	(20.40, 37.84)	(15.00, 37.36)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.94 (7.212)
95% C.I.		(-17.12, 11.23)
p-value		0.683
Corrected Hedge’s g (SE) [1]		-0.12 (0.308)
95% C.I.		(-0.73, 0.48)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.57
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Number of Risk Factors - GBA Approach

Number of risk factors: <=1
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	307	293
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	53 (17%)	56 (19%)
Non-responder	71 (23%)	55 (19%)
Missing [1]	183 (60%)	182 (62%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.88
95% C.I.		(0.58, 1.34)
p-value		0.558
Inverse Relative Risk [3]		0.90
95% C.I.		(0.64, 1.27)
p-value		0.558
Risk Difference (%) [4]		-1.85
95% C.I.		(-8.02, 4.33)
p-value		0.597

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

PPD

Table 24.57
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Number of Risk Factors - GBA Approach

Number of risk factors: 2
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	153	178
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	23 (15%)	47 (26%)
Non-responder	40 (26%)	34 (19%)
Missing [1]	90 (59%)	97 (54%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.49
95% C.I.		(0.28, 0.86)
p-value		0.013
Inverse Relative Risk [3]		0.57
95% C.I.		(0.36, 0.89)
p-value		0.015
Risk Difference (%) [4]		-11.37
95% C.I.		(-19.97, -2.77)
p-value		0.015

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

Table 24.57
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Number of Risk Factors - GBA Approach

Number of risk factors: >=3
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	69	57
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	16 (23%)	9 (16%)
Non-responder	12 (17%)	8 (14%)
Missing [1]	41 (59%)	40 (70%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.61
95% C.I.		(0.65, 3.98)
p-value		0.303
Inverse Relative Risk [3]		1.47
95% C.I.		(0.70, 3.07)
p-value		0.308
Risk Difference (%) [4]		7.40
95% C.I.		(-6.34, 21.14)
p-value		0.372

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.58
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Number of Risk Factors - GBA Approach

Number of risk factors: <=1
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	307	293
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	44 (14%)	48 (16%)
Non-responder	80 (26%)	63 (22%)
Missing [1]	183 (60%)	182 (62%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.85
95% C.I.		(0.55, 1.33)
p-value		0.487
Inverse Relative Risk [3]		0.87
95% C.I.		(0.60, 1.27)
p-value		0.487
Risk Difference (%) [4]		-2.05
95% C.I.		(-7.82, 3.72)
p-value		0.499

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

PPD

Table 24.58
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Number of Risk Factors - GBA Approach

Number of risk factors: 2
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	153	178
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	30 (20%)	40 (22%)
Non-responder	33 (22%)	41 (23%)
Missing [1]	90 (59%)	97 (54%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.84
95% C.I.		(0.49, 1.43)
p-value		0.525
Inverse Relative Risk [3]		0.87
95% C.I.		(0.57, 1.33)
p-value		0.526
Risk Difference (%) [4]		-2.86
95% C.I.		(-11.65, 5.92)
p-value		0.590

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

PPD

Table 24.58
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Number of Risk Factors - GBA Approach

Number of risk factors: >=3
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	69	57
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	9 (13%)	8 (14%)
Non-responder	19 (28%)	9 (16%)
Missing [1]	41 (59%)	40 (70%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.92
95% C.I.		(0.33, 2.56)
p-value		0.872
Inverse Relative Risk [3]		0.93
95% C.I.		(0.38, 2.25)
p-value		0.872
Risk Difference (%) [4]		-0.99
95% C.I.		(-13.01, 11.03)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.59
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Number of Risk Factors - QualityMetric Approach

Number of risk factors: <=1
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	307	293
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	66 (21%)	65 (22%)
Non-responder	58 (19%)	46 (16%)
Missing [1]	183 (60%)	182 (62%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.96
95% C.I.		(0.65, 1.42)
p-value		0.839
Inverse Relative Risk [3]		0.97
95% C.I.		(0.72, 1.31)
p-value		0.839
Risk Difference (%) [4]		-0.69
95% C.I.		(-7.30, 5.93)
p-value		0.844

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

PPD

Table 24.59
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Number of Risk Factors - QualityMetric Approach

Number of risk factors: 2
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	153	178
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	30 (20%)	52 (29%)
Non-responder	33 (22%)	29 (16%)
Missing [1]	90 (59%)	97 (54%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.59
95% C.I.		(0.35, 0.99)
p-value		0.045
Inverse Relative Risk [3]		0.67
95% C.I.		(0.45, 1.00)
p-value		0.048
Risk Difference (%) [4]		-9.61
95% C.I.		(-18.78, -0.43)
p-value		0.056

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

Table 24.59
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Number of Risk Factors - QualityMetric Approach

Number of risk factors: >=3
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	69	57
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	17 (25%)	10 (18%)
Non-responder	11 (16%)	7 (12%)
Missing [1]	41 (59%)	40 (70%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.54
95% C.I.		(0.64, 3.69)
p-value		0.337
Inverse Relative Risk [3]		1.40
95% C.I.		(0.70, 2.82)
p-value		0.341
Risk Difference (%) [4]		7.09
95% C.I.		(-7.08, 21.27)
p-value		0.388

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.60
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Number of Risk Factors - QualityMetric Approach

Number of risk factors: <=1
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	307	293
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	58 (19%)	61 (21%)
Non-responder	66 (21%)	50 (17%)
Missing [1]	183 (60%)	182 (62%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.89
95% C.I.		(0.59, 1.32)
p-value		0.555
Inverse Relative Risk [3]		0.91
95% C.I.		(0.66, 1.25)
p-value		0.555
Risk Difference (%) [4]		-1.93
95% C.I.		(-8.31, 4.46)
p-value		0.609

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.60
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Number of Risk Factors - QualityMetric Approach

Number of risk factors: 2
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	153	178
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	34 (22%)	45 (25%)
Non-responder	29 (19%)	36 (20%)
Missing [1]	90 (59%)	97 (54%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.84
95% C.I.		(0.51, 1.41)
p-value		0.516
Inverse Relative Risk [3]		0.88
95% C.I.		(0.60, 1.30)
p-value		0.517
Risk Difference (%) [4]		-3.06
95% C.I.		(-12.23, 6.12)
p-value		0.606

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.60
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Number of Risk Factors - QualityMetric Approach

Number of risk factors: >=3
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	69	57
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	12 (17%)	9 (16%)
Non-responder	16 (23%)	8 (14%)
Missing [1]	41 (59%)	40 (70%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.12
95% C.I.		(0.44, 2.89)
p-value		0.811
Inverse Relative Risk [3]		1.10
95% C.I.		(0.50, 2.43)
p-value		0.811
Risk Difference (%) [4]		1.60
95% C.I.		(-11.42, 14.62)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, number of risk factors (<=1, 2, >=3) and number of risk factors by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		231	234
Baseline	SF-12 Score	n	200	208
		Mean	66.38	65.63
		SD	29.612	27.405
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	127	124
		Mean	85.63	86.29
		SD	21.712	22.622
		Median	100.00	100.00
		Min.	25.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	116	117
		Mean	18.32	21.58
		SD	32.531	33.941
		Median	0.00	25.00
		Min.	-50.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	46.47	46.24
		SD	9.322	8.627
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	127	124
		Mean	52.54	52.74
		SD	6.835	7.121
		Median	57.06	57.06
		Min.	33.5	33.5
		Max.	57.1	57.1
	Change from Baseline	n	116	117
		Mean	5.77	6.79
		SD	10.241	10.685
		Median	0.00	7.87
		Min.	-15.7	-23.6
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	60.25	62.20
		SD	23.603	24.371
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	127	124
		Mean	81.59	85.28
		SD	21.001	21.800
		Median	87.50	100.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	116	117
		Mean	24.14	24.15
		SD	25.735	29.531
		Median	25.00	25.00
		Min.	-50.0	-62.5
		Max.	100.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	44.01	44.67
		SD	7.989	8.250
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	127	124
		Mean	51.23	52.48
		SD	7.107	7.378
		Median	53.23	57.46
		Min.	32.1	23.6
		Max.	57.5	57.5
	Change from Baseline	n	116	117
		Mean	8.17	8.17
		SD	8.711	9.996
		Median	8.46	8.46
		Min.	-16.9	-21.2
		Max.	33.9	25.4

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	73.38	69.95
		SD	24.309	25.391
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	127	124
		Mean	89.96	92.94
		SD	17.890	16.429
		Median	100.00	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	116	117
		Mean	18.10	23.72
		SD	23.908	28.400
		Median	25.00	25.00
		Min.	-50.0	-75.0
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	48.12	46.89
		SD	8.771	9.161
		Median	48.71	48.71
		Min.	21.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	127	124
		Mean	54.11	55.18
		SD	6.454	5.928
		Median	57.73	57.73
		Min.	21.7	30.7
		Max.	57.7	57.7
	Change from Baseline	n	116	117
		Mean	6.53	8.56
		SD	8.626	10.247
		Median	9.02	9.02
		Min.	-18.0	-27.1
		Max.	27.1	27.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	60.30	59.35
		SD	24.799	26.112
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	127	124
		Mean	73.62	70.24
		SD	17.225	18.378
		Median	60.00	60.00
		Min.	25.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	116	117
		Mean	12.80	10.64
		SD	22.168	28.082
		Median	0.00	0.00
		Min.	-35.0	-40.0
		Max.	85.0	85.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	47.87	47.49
		SD	9.859	10.381
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	127	124
		Mean	53.17	51.82
		SD	6.850	7.308
		Median	47.75	47.75
		Min.	33.8	33.8
		Max.	63.7	63.7
	Change from Baseline	n	116	117
		Mean	5.09	4.23
		SD	8.813	11.165
		Median	0.00	0.00
		Min.	-13.9	-15.9
		Max.	33.8	33.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	46.25	47.36
		SD	24.652	26.219
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	127	123
		Mean	68.90	69.31
		SD	28.819	32.614
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	116	117
		Mean	24.35	20.30
		SD	30.833	36.838
		Median	25.00	25.00
		Min.	-50.0	-100.0
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	47.59	48.03
		SD	9.700	10.316
		Median	49.07	49.07
		Min.	29.4	29.4
		Max.	68.7	68.7
Day 29	SF-12 Score	n	127	123
		Mean	56.50	56.66
		SD	11.339	12.833
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	116	117
		Mean	9.58	7.99
		SD	12.132	14.494
		Median	9.84	9.84
		Min.	-19.7	-39.3
		Max.	29.5	29.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	54.88	57.21
		SD	34.337	34.081
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	127	124
		Mean	86.42	90.12
		SD	21.537	21.813
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	116	117
		Mean	31.47	31.84
		SD	37.318	37.804
		Median	25.00	25.00
		Min.	-50.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	40.85	41.68
		SD	12.217	12.126
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	127	124
		Mean	52.07	53.39
		SD	7.662	7.760
		Median	56.90	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	116	117
		Mean	11.20	11.33
		SD	13.277	13.450
		Median	8.90	8.90
		Min.	-17.8	-26.7
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	69.44	73.26
		SD	25.022	24.680
		Median	68.75	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	127	124
		Mean	89.37	91.73
		SD	17.040	18.919
		Median	100.00	100.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	116	117
		Mean	20.26	19.66
		SD	25.305	27.578
		Median	12.50	12.50
		Min.	-25.0	-62.5
		Max.	75.0	87.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	43.57	45.16
		SD	10.405	10.262
		Median	43.29	45.89
		Min.	14.7	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	127	124
		Mean	51.86	52.84
		SD	7.085	7.866
		Median	56.28	56.28
		Min.	25.1	14.7
		Max.	56.3	56.3
	Change from Baseline	n	116	117
		Mean	8.42	8.17
		SD	10.523	11.467
		Median	5.20	5.20
		Min.	-10.4	-26.0
		Max.	31.2	36.4

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	63.63	65.69
		SD	20.712	21.867
		Median	62.50	62.50
		Min.	25.0	12.5
		Max.	100.0	100.0
Day 29	SF-12 Score	n	127	124
		Mean	78.05	79.64
		SD	20.757	20.750
		Median	87.50	87.50
		Min.	37.5	12.5
		Max.	100.0	100.0
	Change from Baseline	n	116	117
		Mean	15.30	16.03
		SD	24.511	27.161
		Median	12.50	12.50
		Min.	-37.5	-50.0
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	47.52	48.46
		SD	9.506	10.036
		Median	47.00	47.00
		Min.	29.8	24.1
		Max.	64.2	64.2
Day 29	SF-12 Score	n	127	124
		Mean	54.14	54.86
		SD	9.526	9.523
		Median	58.47	58.47
		Min.	35.5	24.1
		Max.	64.2	64.2
	Change from Baseline	n	116	117
		Mean	7.02	7.36
		SD	11.250	12.466
		Median	5.73	5.74
		Min.	-17.2	-23.0
		Max.	34.4	34.4

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	47.06	46.19
		SD	7.426	7.386
		Median	46.72	44.70
		Min.	25.5	24.8
		Max.	62.6	62.7
Day 29	SF-12 Score	n	127	124
		Mean	52.50	52.68
		SD	5.865	6.545
		Median	53.65	53.65
		Min.	35.0	28.9
		Max.	63.4	62.7
	Change from Baseline	n	116	117
		Mean	5.68	6.48
		SD	7.621	8.497
		Median	4.51	6.79
		Min.	-13.3	-17.8
		Max.	31.0	25.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	44.74	46.32
		SD	9.128	9.162
		Median	42.76	45.15
		Min.	23.6	15.8
		Max.	73.0	65.4
Day 29	SF-12 Score	n	127	124
		Mean	53.72	54.57
		SD	8.270	7.767
		Median	55.06	55.57
		Min.	34.0	30.4
		Max.	65.6	66.8
	Change from Baseline	n	116	117
		Mean	9.28	8.58
		SD	10.454	11.129
		Median	8.14	8.52
		Min.	-18.4	-20.6
		Max.	33.5	41.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	0.689	0.690
		SD	0.1136	0.1205
		Median	0.657	0.657
		Min.	0.47	0.45
		Max.	1.00	1.00
Day 29	SF-12 Score	n	127	123
		Mean	0.831	0.865
		SD	0.1387	0.1308
		Median	0.859	0.922
		Min.	0.58	0.51
		Max.	1.00	1.00
	Change from Baseline	n	116	117
		Mean	0.154	0.174
		SD	0.1545	0.1813
		Median	0.131	0.179
		Min.	-0.23	-0.31
		Max.	0.48	0.45

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	58.59	59.59
		SD	22.324	24.154
		Median	50.00	50.00
		Min.	6.3	6.3
		Max.	100.0	100.0
Day 29	SF-12 Score	n	127	124
		Mean	83.12	87.10
		SD	19.115	19.824
		Median	87.50	100.00
		Min.	25.0	12.5
		Max.	100.0	100.0
	Change from Baseline	n	116	117
		Mean	26.67	28.47
		SD	23.636	27.162
		Median	25.00	31.25
		Min.	-31.3	-56.3
		Max.	93.8	87.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	42.28	42.64
		SD	8.020	8.679
		Median	39.19	39.19
		Min.	23.5	23.5
		Max.	57.2	57.2
Day 29	SF-12 Score	n	127	124
		Mean	51.09	52.52
		SD	6.870	7.124
		Median	52.66	57.16
		Min.	30.2	25.7
		Max.	57.2	57.2
	Change from Baseline	n	116	117
		Mean	9.58	10.23
		SD	8.493	9.760
		Median	8.98	11.23
		Min.	-11.2	-20.2
		Max.	33.7	31.4

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	51.44	52.55
		SD	20.291	21.060
		Median	50.00	50.00
		Min.	6.3	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	127	124
		Mean	75.15	77.49
		SD	21.427	22.073
		Median	75.00	81.25
		Min.	25.0	12.5
		Max.	100.0	100.0
	Change from Baseline	n	116	117
		Mean	26.40	25.43
		SD	23.270	27.314
		Median	25.00	25.00
		Min.	-50.0	-50.0
		Max.	81.3	93.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	200	208
		Mean	47.34	47.87
		SD	9.645	10.010
		Median	46.66	46.66
		Min.	25.9	22.9
		Max.	70.4	70.4
Day 29	SF-12 Score	n	127	124
		Mean	58.61	59.72
		SD	10.182	10.490
		Median	58.54	61.51
		Min.	34.8	28.8
		Max.	70.4	70.4
	Change from Baseline	n	116	117
		Mean	12.55	12.08
		SD	11.060	12.981
		Median	11.89	11.89
		Min.	-23.8	-23.8
		Max.	38.6	44.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		206	212
Baseline	SF-12 Score	n	169	169
		Mean	44.62	46.30
		SD	34.334	36.151
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	91
		Mean	74.01	73.08
		SD	30.602	33.381
		Median	100.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	88	84
		Mean	21.98	25.60
		SD	39.676	41.612
		Median	25.00	25.00
		Min.	-50.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	39.63	40.16
		SD	10.809	11.380
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	101	91
		Mean	48.88	48.58
		SD	9.634	10.508
		Median	57.06	49.19
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	88	84
		Mean	6.92	8.06
		SD	12.490	13.099
		Median	7.87	7.87
		Min.	-15.7	-31.5
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	39.79	39.57
		SD	27.163	28.598
		Median	37.50	37.50
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	91
		Mean	74.13	73.90
		SD	26.766	28.966
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	88	84
		Mean	30.54	36.76
		SD	34.265	36.059
		Median	37.50	37.50
		Min.	-50.0	-25.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	37.08	37.01
		SD	9.196	9.682
		Median	36.30	36.30
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	101	91
		Mean	48.71	48.63
		SD	9.060	9.805
		Median	49.00	49.00
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	88	84
		Mean	10.34	12.44
		SD	11.599	12.207
		Median	12.70	12.70
		Min.	-16.9	-8.5
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	168	169
		Mean	50.00	49.56
		SD	28.824	31.749
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	91
		Mean	83.66	82.14
		SD	25.845	26.689
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	88	84
		Mean	31.53	32.44
		SD	34.008	35.308
		Median	25.00	25.00
		Min.	-50.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	168	169
		Mean	39.69	39.53
		SD	10.399	11.453
		Median	39.69	39.69
		Min.	21.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	101	91
		Mean	51.84	51.29
		SD	9.323	9.629
		Median	57.73	57.73
		Min.	21.7	21.7
		Max.	57.7	57.7
	Change from Baseline	n	88	84
		Mean	11.38	11.70
		SD	12.269	12.738
		Median	9.02	9.02
		Min.	-18.0	-18.0
		Max.	36.1	36.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	50.33	46.54
		SD	31.567	31.434
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	91
		Mean	69.50	65.99
		SD	23.081	21.644
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	88	84
		Mean	14.38	17.32
		SD	29.496	35.892
		Median	0.00	0.00
		Min.	-60.0	-100.0
		Max.	85.0	85.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	43.91	42.40
		SD	12.549	12.496
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	101	91
		Mean	51.53	50.13
		SD	9.177	8.605
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
	Change from Baseline	n	88	84
		Mean	5.71	6.89
		SD	11.726	14.268
		Median	0.00	0.00
		Min.	-23.8	-39.8
		Max.	33.8	33.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	25.44	24.11
		SD	27.613	24.984
		Median	25.00	25.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	91
		Mean	51.49	63.46
		SD	30.988	32.126
		Median	50.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	88	84
		Mean	26.99	41.96
		SD	33.093	38.253
		Median	25.00	50.00
		Min.	-50.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	39.40	38.88
		SD	10.866	9.832
		Median	39.23	39.23
		Min.	29.4	29.4
		Max.	68.7	68.7
Day 29	SF-12 Score	n	101	91
		Mean	49.65	54.36
		SD	12.193	12.640
		Median	49.07	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	88	84
		Mean	10.62	16.51
		SD	13.022	15.051
		Median	9.84	19.67
		Min.	-19.7	-39.3
		Max.	39.3	39.3

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	39.79	32.54
		SD	36.638	33.608
		Median	25.00	25.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	91
		Mean	76.73	81.87
		SD	29.635	27.905
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	88	84
		Mean	36.36	51.79
		SD	42.701	41.396
		Median	50.00	50.00
		Min.	-75.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	35.48	32.90
		SD	13.036	11.958
		Median	30.22	30.22
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	101	91
		Mean	48.62	50.45
		SD	10.543	9.928
		Median	56.90	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	88	84
		Mean	12.94	18.42
		SD	15.192	14.728
		Median	17.79	17.79
		Min.	-26.7	-17.8
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	59.62	58.65
		SD	29.756	32.818
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	91
		Mean	80.07	83.65
		SD	26.878	24.202
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	88	84
		Mean	16.19	24.55
		SD	31.836	36.428
		Median	12.50	25.00
		Min.	-75.0	-50.0
		Max.	87.5	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	39.49	39.09
		SD	12.374	13.647
		Median	35.49	35.49
		Min.	14.7	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	101	91
		Mean	48.00	49.48
		SD	11.176	10.063
		Median	56.28	56.28
		Min.	14.7	14.7
		Max.	56.3	56.3
	Change from Baseline	n	88	84
		Mean	6.73	10.21
		SD	13.238	15.147
		Median	5.19	10.39
		Min.	-31.2	-20.8
		Max.	36.4	41.6

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	52.22	52.22
		SD	22.672	24.142
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	91
		Mean	72.77	77.06
		SD	23.611	21.430
		Median	75.00	87.50
		Min.	12.5	25.0
		Max.	100.0	100.0
	Change from Baseline	n	88	84
		Mean	18.61	27.23
		SD	28.302	31.417
		Median	12.50	25.00
		Min.	-37.5	-25.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	42.28	42.28
		SD	10.404	11.079
		Median	41.26	41.26
		Min.	18.3	18.3
		Max.	64.2	64.2
Day 29	SF-12 Score	n	101	91
		Mean	51.71	53.68
		SD	10.836	9.835
		Median	52.74	58.47
		Min.	24.1	29.8
		Max.	64.2	64.2
	Change from Baseline	n	88	84
		Mean	8.54	12.50
		SD	12.988	14.418
		Median	5.74	11.47
		Min.	-17.2	-11.5
		Max.	34.4	45.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	39.83	39.65
		SD	9.396	9.246
		Median	39.73	39.53
		Min.	17.4	20.2
		Max.	60.5	64.6
Day 29	SF-12 Score	n	101	91
		Mean	50.04	48.77
		SD	8.365	9.234
		Median	51.74	51.15
		Min.	22.7	23.5
		Max.	65.3	69.4
	Change from Baseline	n	88	84
		Mean	8.63	8.84
		SD	9.933	10.252
		Median	8.12	8.26
		Min.	-11.5	-19.7
		Max.	35.6	30.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	40.36	39.31
		SD	10.586	10.806
		Median	40.73	39.15
		Min.	13.8	11.0
		Max.	62.5	69.3
Day 29	SF-12 Score	n	101	91
		Mean	49.73	53.08
		SD	10.828	10.031
		Median	50.71	56.64
		Min.	16.0	20.4
		Max.	64.5	65.0
	Change from Baseline	n	88	84
		Mean	8.98	14.71
		SD	12.266	13.462
		Median	7.19	16.84
		Min.	-12.3	-12.5
		Max.	45.3	43.7

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	168	169
		Mean	0.592	0.581
		SD	0.1109	0.1177
		Median	0.588	0.584
		Min.	0.35	0.35
		Max.	1.00	0.92
Day 29	SF-12 Score	n	101	91
		Mean	0.759	0.804
		SD	0.1481	0.1633
		Median	0.782	0.817
		Min.	0.41	0.48
		Max.	1.00	1.00
	Change from Baseline	n	88	84
		Mean	0.156	0.228
		SD	0.1710	0.1873
		Median	0.125	0.256
		Min.	-0.26	-0.11
		Max.	0.52	0.66

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	38.28	36.35
		SD	26.023	26.879
		Median	37.50	31.25
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	91
		Mean	75.00	75.89
		SD	25.633	26.656
		Median	81.25	81.25
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	88	84
		Mean	34.16	41.96
		SD	32.730	34.894
		Median	43.75	46.88
		Min.	-56.3	-25.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	34.98	34.29
		SD	9.349	9.657
		Median	34.70	32.46
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 29	SF-12 Score	n	101	91
		Mean	48.17	48.50
		SD	9.210	9.578
		Median	50.42	50.42
		Min.	21.2	21.2
		Max.	57.2	57.2
	Change from Baseline	n	88	84
		Mean	12.27	15.08
		SD	11.759	12.537
		Median	15.71	16.84
		Min.	-20.2	-9.0
		Max.	35.9	35.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	28.48	27.07
		SD	22.667	21.701
		Median	25.00	25.00
		Min.	0.0	0.0
		Max.	100.0	93.8
Day 29	SF-12 Score	n	101	91
		Mean	59.84	66.21
		SD	26.389	27.449
		Median	62.50	62.50
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	88	84
		Mean	31.82	42.19
		SD	28.502	28.117
		Median	31.25	43.75
		Min.	-18.8	-12.5
		Max.	93.8	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.66
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	169	169
		Mean	36.43	35.76
		SD	10.776	10.316
		Median	34.77	34.77
		Min.	22.9	22.9
		Max.	70.4	67.5
Day 29	SF-12 Score	n	101	91
		Mean	51.33	54.36
		SD	12.543	13.046
		Median	52.60	52.60
		Min.	22.9	22.9
		Max.	70.4	70.4
	Change from Baseline	n	88	84
		Mean	15.12	20.05
		SD	13.548	13.364
		Median	14.85	20.80
		Min.	-8.9	-5.9
		Max.	44.6	47.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	231	234
n	116	117
LS Mean (SE)	85.05 (2.459)	85.09 (2.429)
95% C.I.	(80.22, 89.89)	(80.32, 89.87)
LS Mean Change from Baseline (SE)	25.76 (2.459)	25.79 (2.429)
95% C.I.	(20.92, 30.59)	(21.02, 30.57)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.04 (3.433)
95% C.I.		(-6.71, 6.79)
p-value		0.991
Corrected Hedge’s g (SE) [1]		0.00 (0.131)
95% C.I.		(-0.26, 0.26)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Role Physical (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	116	117
LS Mean (SE)	81.77 (2.254)	82.90 (2.257)
95% C.I.	(77.34, 86.20)	(78.47, 87.34)
LS Mean Change from Baseline (SE)	30.45 (2.254)	31.58 (2.257)
95% C.I.	(26.01, 34.88)	(27.14, 36.02)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		1.13 (3.137)
95% C.I.		(-5.03, 7.30)
p-value		0.718
Corrected Hedge’s g (SE) [1]		0.05 (0.131)
95% C.I.		(-0.21, 0.30)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	116	117
LS Mean (SE)	88.77 (1.977)	91.64 (1.947)
95% C.I.	(84.88, 92.66)	(87.82, 95.47)
LS Mean Change from Baseline (SE)	26.30 (1.977)	29.17 (1.947)
95% C.I.	(22.42, 30.19)	(25.35, 33.00)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.87 (2.737)
95% C.I.		(-2.51, 8.25)
p-value		0.295
Corrected Hedge’s g (SE) [1]		0.14 (0.131)
95% C.I.		(-0.12, 0.39)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: General Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	116	117
LS Mean (SE)	73.14 (1.812)	70.05 (1.801)
95% C.I.	(69.58, 76.70)	(66.50, 73.59)
LS Mean Change from Baseline (SE)	16.49 (1.812)	13.39 (1.801)
95% C.I.	(12.92, 20.05)	(9.85, 16.93)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-3.09 (2.547)
95% C.I.		(-8.10, 1.91)
p-value		0.225
Corrected Hedge’s g (SE) [1]		-0.16 (0.131)
95% C.I.		(-0.42, 0.10)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Vitality (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	116	117
LS Mean (SE)	66.19 (2.875)	64.72 (2.913)
95% C.I.	(60.54, 71.84)	(58.99, 70.45)
LS Mean Change from Baseline (SE)	29.83 (2.875)	28.36 (2.913)
95% C.I.	(24.18, 35.48)	(22.63, 34.09)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-1.47 (4.002)
95% C.I.		(-9.34, 6.40)
p-value		0.713
Corrected Hedge’s g (SE) [1]		-0.05 (0.131)
95% C.I.		(-0.30, 0.21)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	116	117
LS Mean (SE)	85.65 (2.351)	88.85 (2.357)
95% C.I.	(81.03, 90.27)	(84.22, 93.49)
LS Mean Change from Baseline (SE)	38.12 (2.351)	41.32 (2.357)
95% C.I.	(33.50, 42.74)	(36.69, 45.96)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.21 (3.297)
95% C.I.		(-3.28, 9.69)
p-value		0.331
Corrected Hedge’s g (SE) [1]		0.13 (0.131)
95% C.I.		(-0.13, 0.38)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	116	117
LS Mean (SE)	88.83 (1.967)	90.37 (1.967)
95% C.I.	(84.96, 92.70)	(86.50, 94.24)
LS Mean Change from Baseline (SE)	22.10 (1.967)	23.64 (1.967)
95% C.I.	(18.23, 25.97)	(19.77, 27.51)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		1.54 (2.775)
95% C.I.		(-3.92, 6.99)
p-value		0.580
Corrected Hedge’s g (SE) [1]		0.07 (0.131)
95% C.I.		(-0.18, 0.33)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Mental Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	116	117
LS Mean (SE)	77.30 (1.966)	80.25 (1.974)
95% C.I.	(73.44, 81.17)	(76.37, 84.13)
LS Mean Change from Baseline (SE)	18.35 (1.966)	21.30 (1.974)
95% C.I.	(14.49, 22.22)	(17.42, 25.18)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.95 (2.766)
95% C.I.		(-2.49, 8.39)
p-value		0.287
Corrected Hedge’s g (SE) [1]		0.14 (0.131)
95% C.I.		(-0.12, 0.40)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Physical Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	116	117
LS Mean (SE)	52.08 (0.662)	51.93 (0.649)
95% C.I.	(50.77, 53.38)	(50.65, 53.20)
LS Mean Change from Baseline (SE)	8.04 (0.662)	7.89 (0.649)
95% C.I.	(6.74, 9.34)	(6.61, 9.17)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.15 (0.914)
95% C.I.		(-1.94, 1.65)
p-value		0.871
Corrected Hedge’s g (SE) [1]		-0.02 (0.131)
95% C.I.		(-0.28, 0.24)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Mental Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	116	117
LS Mean (SE)	53.22 (0.835)	54.18 (0.844)
95% C.I.	(51.58, 54.86)	(52.52, 55.84)
LS Mean Change from Baseline (SE)	10.33 (0.835)	11.29 (0.844)
95% C.I.	(8.69, 11.97)	(9.63, 12.95)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.96 (1.179)
95% C.I.		(-1.36, 3.28)
p-value		0.416
Corrected Hedge’s g (SE) [1]		0.11 (0.131)
95% C.I.		(-0.15, 0.36)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Health Utility Index

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	116	117
LS Mean (SE)	0.83 (0.014)	0.86 (0.014)
95% C.I.	(0.80, 0.86)	(0.83, 0.88)
LS Mean Change from Baseline (SE)	0.19 (0.014)	0.21 (0.014)
95% C.I.	(0.16, 0.21)	(0.19, 0.24)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.03 (0.019)
95% C.I.		(-0.01, 0.06)
p-value		0.164
Corrected Hedge’s g (SE) [1]		0.18 (0.131)
95% C.I.		(-0.08, 0.44)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	116	117
LS Mean (SE)	82.53 (2.099)	84.79 (2.096)
95% C.I.	(78.41, 86.66)	(80.67, 88.91)
LS Mean Change from Baseline (SE)	33.49 (2.099)	35.75 (2.096)
95% C.I.	(29.36, 37.62)	(31.63, 39.87)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.26 (2.910)
95% C.I.		(-3.46, 7.98)
p-value		0.438
Corrected Hedge’s g (SE) [1]		0.10 (0.131)
95% C.I.		(-0.16, 0.36)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	116	117
LS Mean (SE)	72.27 (2.233)	72.98 (2.265)
95% C.I.	(67.89, 76.66)	(68.53, 77.44)
LS Mean Change from Baseline (SE)	32.34 (2.233)	33.05 (2.265)
95% C.I.	(27.95, 36.73)	(28.59, 37.50)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.71 (3.063)
95% C.I.		(-5.31, 6.73)
p-value		0.817
Corrected Hedge’s g (SE) [1]		0.03 (0.131)
95% C.I.		(-0.23, 0.29)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	206	212
n	88	84
LS Mean (SE)	75.31 (2.806)	75.01 (2.900)
95% C.I.	(69.79, 80.82)	(69.31, 80.71)
LS Mean Change from Baseline (SE)	16.01 (2.806)	15.71 (2.900)
95% C.I.	(10.49, 21.53)	(10.01, 21.41)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.30 (3.997)
95% C.I.		(-8.15, 7.56)
p-value		0.941
Corrected Hedge’s g (SE) [1]		-0.01 (0.153)
95% C.I.		(-0.31, 0.29)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Role Physical (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	88	84
LS Mean (SE)	74.61 (2.588)	76.63 (2.701)
95% C.I.	(69.52, 79.70)	(71.32, 81.94)
LS Mean Change from Baseline (SE)	23.28 (2.588)	25.30 (2.701)
95% C.I.	(18.19, 28.37)	(19.99, 30.61)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.02 (3.660)
95% C.I.		(-5.17, 9.21)
p-value		0.581
Corrected Hedge’s g (SE) [1]		0.08 (0.153)
95% C.I.		(-0.22, 0.38)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	88	84
LS Mean (SE)	85.78 (2.259)	84.61 (2.330)
95% C.I.	(81.33, 90.22)	(80.03, 89.19)
LS Mean Change from Baseline (SE)	23.31 (2.259)	22.14 (2.330)
95% C.I.	(18.87, 27.75)	(17.56, 26.72)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-1.17 (3.184)
95% C.I.		(-7.43, 5.09)
p-value		0.714
Corrected Hedge’s g (SE) [1]		-0.05 (0.153)
95% C.I.		(-0.35, 0.24)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: General Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	88	84
LS Mean (SE)	69.38 (2.073)	66.78 (2.146)
95% C.I.	(65.31, 73.46)	(62.56, 71.00)
LS Mean Change from Baseline (SE)	12.73 (2.073)	10.13 (2.146)
95% C.I.	(8.65, 16.81)	(5.91, 14.35)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.60 (2.976)
95% C.I.		(-8.45, 3.25)
p-value		0.382
Corrected Hedge’s g (SE) [1]		-0.13 (0.153)
95% C.I.		(-0.43, 0.17)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Vitality (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	88	84
LS Mean (SE)	54.68 (3.345)	68.61 (3.443)
95% C.I.	(48.10, 61.25)	(61.84, 75.38)
LS Mean Change from Baseline (SE)	18.32 (3.345)	32.25 (3.443)
95% C.I.	(11.74, 24.90)	(25.48, 39.02)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		13.93 (4.652)
95% C.I.		(4.79, 23.08)
p-value		0.003
Corrected Hedge’s g (SE) [1]		0.44 (0.154)
95% C.I.		(0.14, 0.74)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	88	84
LS Mean (SE)	77.20 (2.695)	83.93 (2.816)
95% C.I.	(71.90, 82.50)	(78.40, 89.47)
LS Mean Change from Baseline (SE)	29.67 (2.695)	36.40 (2.816)
95% C.I.	(24.37, 34.97)	(30.86, 41.94)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		6.73 (3.852)
95% C.I.		(-0.84, 14.31)
p-value		0.081
Corrected Hedge’s g (SE) [1]		0.26 (0.153)
95% C.I.		(-0.04, 0.56)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	88	84
LS Mean (SE)	80.83 (2.259)	85.39 (2.328)
95% C.I.	(76.39, 85.27)	(80.81, 89.96)
LS Mean Change from Baseline (SE)	14.10 (2.259)	18.66 (2.328)
95% C.I.	(9.66, 18.54)	(14.08, 23.23)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.56 (3.234)
95% C.I.		(-1.80, 10.92)
p-value		0.159
Corrected Hedge’s g (SE) [1]		0.21 (0.153)
95% C.I.		(-0.09, 0.51)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Mental Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	88	84
LS Mean (SE)	73.65 (2.259)	78.72 (2.342)
95% C.I.	(69.21, 78.09)	(74.12, 83.32)
LS Mean Change from Baseline (SE)	14.70 (2.259)	19.77 (2.342)
95% C.I.	(10.26, 19.14)	(15.17, 24.37)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		5.07 (3.223)
95% C.I.		(-1.26, 11.41)
p-value		0.116
Corrected Hedge’s g (SE) [1]		0.24 (0.153)
95% C.I.		(-0.06, 0.54)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Physical Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	88	84
LS Mean (SE)	50.62 (0.752)	49.80 (0.782)
95% C.I.	(49.14, 52.09)	(48.26, 51.34)
LS Mean Change from Baseline (SE)	6.58 (0.752)	5.76 (0.782)
95% C.I.	(5.10, 8.06)	(4.23, 7.30)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.81 (1.063)
95% C.I.		(-2.91, 1.28)
p-value		0.444
Corrected Hedge’s g (SE) [1]		-0.11 (0.153)
95% C.I.		(-0.41, 0.19)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Mental Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	88	84
LS Mean (SE)	50.16 (0.961)	54.14 (0.999)
95% C.I.	(48.27, 52.05)	(52.18, 56.11)
LS Mean Change from Baseline (SE)	7.27 (0.961)	11.26 (0.999)
95% C.I.	(5.38, 9.16)	(9.30, 13.23)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.99 (1.371)
95% C.I.		(1.29, 6.68)
p-value		0.004
Corrected Hedge’s g (SE) [1]		0.44 (0.154)
95% C.I.		(0.13, 0.74)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Health Utility Index

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	88	84
LS Mean (SE)	0.76 (0.016)	0.81 (0.016)
95% C.I.	(0.73, 0.80)	(0.78, 0.85)
LS Mean Change from Baseline (SE)	0.12 (0.016)	0.17 (0.016)
95% C.I.	(0.09, 0.15)	(0.14, 0.20)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.05 (0.022)
95% C.I.		(0.01, 0.09)
p-value		0.026
Corrected Hedge’s g (SE) [1]		0.33 (0.154)
95% C.I.		(0.03, 0.63)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	88	84
LS Mean (SE)	75.92 (2.405)	79.09 (2.520)
95% C.I.	(71.19, 80.64)	(74.14, 84.05)
LS Mean Change from Baseline (SE)	26.87 (2.405)	30.05 (2.520)
95% C.I.	(22.15, 31.60)	(25.10, 35.00)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.18 (3.398)
95% C.I.		(-3.51, 9.86)
p-value		0.351
Corrected Hedge’s g (SE) [1]		0.14 (0.153)
95% C.I.		(-0.16, 0.44)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.67
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	88	84
LS Mean (SE)	63.77 (2.591)	71.68 (2.716)
95% C.I.	(58.68, 68.86)	(66.35, 77.02)
LS Mean Change from Baseline (SE)	23.83 (2.591)	31.75 (2.716)
95% C.I.	(18.74, 28.92)	(26.41, 37.08)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		7.92 (3.568)
95% C.I.		(0.90, 14.93)
p-value		0.027
Corrected Hedge’s g (SE) [1]		0.32 (0.154)
95% C.I.		(0.02, 0.62)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.68
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Patient Reported Symptom Severity - GBA Approach

Patient reported symptom severity: <2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	231	234
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	51 (22%)	53 (23%)
Non-responder	65 (28%)	64 (27%)
Missing [1]	115 (50%)	117 (50%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.97
95% C.I.		(0.63, 1.50)
p-value		0.883
Inverse Relative Risk [3]		0.97
95% C.I.		(0.69, 1.37)
p-value		0.883
Risk Difference (%) [4]		-0.57
95% C.I.		(-8.15, 7.00)
p-value		0.912

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

PPD

Table 24.68
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Patient Reported Symptom Severity - GBA Approach

Patient reported symptom severity: >=2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	206	212
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	38 (18%)	55 (26%)
Non-responder	50 (24%)	29 (14%)
Missing [1]	118 (57%)	128 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.65
95% C.I.		(0.40, 1.03)
p-value		0.067
Inverse Relative Risk [3]		0.71
95% C.I.		(0.49, 1.03)
p-value		0.069
Risk Difference (%) [4]		-7.50
95% C.I.		(-15.43, 0.43)
p-value		0.078

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.69
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Patient Reported Symptom Severity - GBA Approach

Patient reported symptom severity: <2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	231	234
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	37 (16%)	51 (22%)
Non-responder	79 (34%)	66 (28%)
Missing [1]	115 (50%)	117 (50%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.68
95% C.I.		(0.43, 1.09)
p-value		0.113
Inverse Relative Risk [3]		0.73
95% C.I.		(0.50, 1.08)
p-value		0.115
Risk Difference (%) [4]		-5.78
95% C.I.		(-12.87, 1.32)
p-value		0.125

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.69
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Patient Reported Symptom Severity - GBA Approach

Patient reported symptom severity: >=2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	206	212
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	43 (21%)	41 (19%)
Non-responder	45 (22%)	43 (20%)
Missing [1]	118 (57%)	128 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.10
95% C.I.		(0.68, 1.78)
p-value		0.696
Inverse Relative Risk [3]		1.08
95% C.I.		(0.74, 1.58)
p-value		0.696
Risk Difference (%) [4]		1.53
95% C.I.		(-6.15, 9.22)
p-value		0.716

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

PPD

Table 24.70
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Patient Reported Symptom Severity - QualityMetric Approach

Patient reported symptom severity: <2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	231	234
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	65 (28%)	65 (28%)
Non-responder	51 (22%)	52 (22%)
Missing [1]	115 (50%)	117 (50%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.02
95% C.I.		(0.68, 1.53)
p-value		0.931
Inverse Relative Risk [3]		1.01
95% C.I.		(0.76, 1.36)
p-value		0.931
Risk Difference (%) [4]		0.36
95% C.I.		(-7.80, 8.52)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

PPD

Table 24.70
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Patient Reported Symptom Severity - QualityMetric Approach

Patient reported symptom severity: >=2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	206	212
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	45 (22%)	58 (27%)
Non-responder	43 (21%)	26 (12%)
Missing [1]	118 (57%)	128 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.74
95% C.I.		(0.47, 1.16)
p-value		0.192
Inverse Relative Risk [3]		0.80
95% C.I.		(0.57, 1.12)
p-value		0.193
Risk Difference (%) [4]		-5.51
95% C.I.		(-13.75, 2.72)
p-value		0.213

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.71
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Patient Reported Symptom Severity - QualityMetric Approach

Patient reported symptom severity: <2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	231	234
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	50 (22%)	61 (26%)
Non-responder	66 (29%)	56 (24%)
Missing [1]	115 (50%)	117 (50%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.78
95% C.I.		(0.51, 1.20)
p-value		0.264
Inverse Relative Risk [3]		0.83
95% C.I.		(0.60, 1.15)
p-value		0.265
Risk Difference (%) [4]		-4.42
95% C.I.		(-12.16, 3.31)
p-value		0.279

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Table 24.71
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Patient Reported Symptom Severity - QualityMetric Approach

Patient reported symptom severity: >=2 moderate/higher intensity
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	206	212
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	51 (25%)	49 (23%)
Non-responder	37 (18%)	35 (17%)
Missing [1]	118 (57%)	128 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		1.09
95% C.I.		(0.70, 1.72)
p-value		0.694
Inverse Relative Risk [3]		1.07
95% C.I.		(0.76, 1.51)
p-value		0.694
Risk Difference (%) [4]		1.64
95% C.I.		(-6.54, 9.83)
p-value		0.732

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, patient reported symptom severity (<2, >=2) and patient reported symptom severity by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		15	14
Baseline	SF-12 Score	n	9	11
		Mean	66.67	65.91
		SD	37.500	37.538
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	5	7
		Mean	65.00	85.71
		SD	41.833	28.347
		Median	75.00	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	5	6
		Mean	-5.00	12.50
		SD	41.079	20.917
		Median	0.00	0.00
		Min.	-75.0	0.0
		Max.	25.0	50.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	46.57	46.33
		SD	11.805	11.817
		Median	49.19	49.19
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	5	7
		Mean	46.04	52.56
		SD	13.169	8.924
		Median	49.19	57.06
		Min.	25.6	33.5
		Max.	57.1	57.1
	Change from Baseline	n	5	6
		Mean	-1.57	3.94
		SD	12.932	6.585
		Median	0.00	0.00
		Min.	-23.6	0.0
		Max.	7.9	15.7

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	43.06	52.27
		SD	31.937	30.009
		Median	50.00	50.00
		Min.	0.0	12.5
		Max.	100.0	100.0
Day 29	SF-12 Score	n	5	7
		Mean	52.50	75.00
		SD	31.125	30.619
		Median	62.50	87.50
		Min.	0.0	12.5
		Max.	75.0	100.0
	Change from Baseline	n	5	6
		Mean	15.00	27.08
		SD	40.889	33.927
		Median	37.50	12.50
		Min.	-50.0	0.0
		Max.	50.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	38.19	41.31
		SD	10.812	10.159
		Median	40.54	40.54
		Min.	23.6	27.8
		Max.	57.5	57.5
Day 29	SF-12 Score	n	5	7
		Mean	41.38	49.00
		SD	10.537	10.365
		Median	44.77	53.23
		Min.	23.6	27.8
		Max.	49.0	57.5
	Change from Baseline	n	5	6
		Mean	5.08	9.17
		SD	13.846	11.486
		Median	12.70	4.23
		Min.	-16.9	0.0
		Max.	16.9	25.4

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	69.44	59.09
		SD	32.543	28.002
		Median	75.00	50.00
		Min.	25.0	25.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	5	7
		Mean	90.00	85.71
		SD	13.693	19.670
		Median	100.00	100.00
		Min.	75.0	50.0
		Max.	100.0	100.0
	Change from Baseline	n	5	6
		Mean	20.00	29.17
		SD	32.596	36.799
		Median	0.00	12.50
		Min.	0.0	0.0
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	46.71	42.97
		SD	11.741	10.103
		Median	48.71	39.69
		Min.	30.7	30.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	5	7
		Mean	54.12	52.58
		SD	4.940	7.097
		Median	57.73	57.73
		Min.	48.7	39.7
		Max.	57.7	57.7
	Change from Baseline	n	5	6
		Mean	7.22	10.52
		SD	11.761	13.277
		Median	0.00	4.51
		Min.	0.0	0.0
		Max.	27.1	27.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	63.33	53.18
		SD	24.622	25.717
		Median	60.00	60.00
		Min.	25.0	25.0
		Max.	85.0	100.0
Day 29	SF-12 Score	n	5	7
		Mean	44.00	60.00
		SD	27.477	0.000
		Median	25.00	60.00
		Min.	25.0	60.0
		Max.	85.0	60.0
	Change from Baseline	n	5	6
		Mean	-24.00	17.50
		SD	25.348	19.170
		Median	-25.00	17.50
		Min.	-60.0	0.0
		Max.	0.0	35.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	49.08	45.04
		SD	9.787	10.224
		Median	47.75	47.75
		Min.	33.8	33.8
		Max.	57.7	63.7
Day 29	SF-12 Score	n	5	7
		Mean	41.39	47.75
		SD	10.922	0.000
		Median	33.84	47.75
		Min.	33.8	47.8
		Max.	57.7	47.8
	Change from Baseline	n	5	6
		Mean	-9.54	6.95
		SD	10.075	7.619
		Median	-9.94	6.95
		Min.	-23.8	0.0
		Max.	0.0	13.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	36.11	59.09
		SD	30.901	28.002
		Median	25.00	50.00
		Min.	0.0	25.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	5	7
		Mean	35.00	71.43
		SD	28.504	9.449
		Median	25.00	75.00
		Min.	0.0	50.0
		Max.	75.0	75.0
	Change from Baseline	n	5	6
		Mean	15.00	8.33
		SD	13.693	30.277
		Median	25.00	12.50
		Min.	0.0	-25.0
		Max.	25.0	50.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	43.60	52.64
		SD	12.160	11.017
		Median	39.23	49.07
		Min.	29.4	39.2
		Max.	68.7	68.7
Day 29	SF-12 Score	n	5	7
		Mean	43.16	57.50
		SD	11.216	3.715
		Median	39.23	58.90
		Min.	29.4	49.1
		Max.	58.9	58.9
	Change from Baseline	n	5	6
		Mean	5.90	3.28
		SD	5.388	11.910
		Median	9.83	4.91
		Min.	0.0	-9.8
		Max.	9.8	19.7

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	30.56	45.45
		SD	42.898	38.435
		Median	0.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	5	7
		Mean	55.00	89.29
		SD	44.721	19.670
		Median	50.00	100.00
		Min.	0.0	50.0
		Max.	100.0	100.0
	Change from Baseline	n	5	6
		Mean	45.00	50.00
		SD	57.009	41.833
		Median	50.00	37.50
		Min.	-25.0	0.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	32.19	37.49
		SD	15.263	13.676
		Median	21.32	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	5	7
		Mean	40.89	53.09
		SD	15.911	6.998
		Median	39.11	56.90
		Min.	21.3	39.1
		Max.	56.9	56.9
	Change from Baseline	n	5	6
		Mean	16.01	17.79
		SD	20.282	14.885
		Median	17.79	13.34
		Min.	-8.9	0.0
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	62.50	80.68
		SD	35.904	20.436
		Median	50.00	75.00
		Min.	12.5	50.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	5	7
		Mean	72.50	94.64
		SD	22.361	9.835
		Median	75.00	100.00
		Min.	50.0	75.0
		Max.	100.0	100.0
	Change from Baseline	n	5	6
		Mean	2.50	8.33
		SD	20.540	20.412
		Median	0.00	12.50
		Min.	-12.5	-25.0
		Max.	37.5	25.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	40.69	48.25
		SD	14.931	8.496
		Median	35.49	45.89
		Min.	19.9	35.5
		Max.	56.3	56.3
Day 29	SF-12 Score	n	5	7
		Mean	44.85	54.05
		SD	9.297	4.088
		Median	45.89	56.28
		Min.	35.5	45.9
		Max.	56.3	56.3
	Change from Baseline	n	5	6
		Mean	1.04	3.46
		SD	8.543	8.483
		Median	0.00	5.20
		Min.	-5.2	-10.4
		Max.	15.6	10.4

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	69.44	69.32
		SD	22.631	17.996
		Median	75.00	75.00
		Min.	25.0	50.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	5	7
		Mean	65.00	78.57
		SD	10.458	17.252
		Median	62.50	87.50
		Min.	50.0	50.0
		Max.	75.0	100.0
	Change from Baseline	n	5	6
		Mean	-5.00	6.25
		SD	16.771	13.110
		Median	-12.50	6.25
		Min.	-25.0	-12.5
		Max.	12.5	25.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	50.19	50.13
		SD	10.386	8.260
		Median	52.74	52.74
		Min.	29.8	41.3
		Max.	64.2	64.2
Day 29	SF-12 Score	n	5	7
		Mean	48.15	54.37
		SD	4.802	7.917
		Median	47.00	58.47
		Min.	41.3	41.3
		Max.	52.7	64.2
	Change from Baseline	n	5	6
		Mean	-2.29	2.87
		SD	7.698	6.016
		Median	-5.74	2.86
		Min.	-11.5	-5.7
		Max.	5.7	11.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	44.82	42.40
		SD	8.387	10.753
		Median	43.89	40.18
		Min.	30.3	27.1
		Max.	55.5	59.6
Day 29	SF-12 Score	n	5	7
		Mean	45.73	49.44
		SD	10.634	7.806
		Median	47.24	51.88
		Min.	28.5	33.1
		Max.	56.4	55.9
	Change from Baseline	n	5	6
		Mean	1.38	8.63
		SD	8.739	9.056
		Median	3.35	7.40
		Min.	-10.8	-0.3
		Max.	13.1	24.4

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	42.34	49.24
		SD	10.027	8.254
		Median	44.37	50.03
		Min.	25.8	35.9
		Max.	55.2	59.9
Day 29	SF-12 Score	n	5	7
		Mean	44.51	55.80
		SD	6.214	5.745
		Median	45.37	57.53
		Min.	37.8	44.6
		Max.	53.4	60.8
	Change from Baseline	n	5	6
		Mean	4.21	5.28
		SD	5.552	8.765
		Median	2.21	5.42
		Min.	-0.8	-5.4
		Max.	13.7	19.0

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	0.642	0.680
		SD	0.1590	0.1457
		Median	0.615	0.657
		Min.	0.47	0.54
		Max.	0.92	1.00
Day 29	SF-12 Score	n	5	7
		Mean	0.672	0.834
		SD	0.0651	0.1121
		Median	0.657	0.863
		Min.	0.60	0.66
		Max.	0.75	0.92
	Change from Baseline	n	5	6
		Mean	0.084	0.137
		SD	0.1110	0.1805
		Median	0.034	0.131
		Min.	-0.02	-0.08
		Max.	0.23	0.37

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	43.75	49.43
		SD	30.298	30.163
		Median	43.75	50.00
		Min.	6.3	18.8
		Max.	100.0	100.0
Day 29	SF-12 Score	n	5	7
		Mean	58.75	77.68
		SD	25.233	26.234
		Median	62.50	81.25
		Min.	18.8	25.0
		Max.	87.5	100.0
	Change from Baseline	n	5	6
		Mean	25.00	34.38
		SD	30.936	33.946
		Median	31.25	25.00
		Min.	-25.0	0.0
		Max.	50.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	36.95	38.99
		SD	10.887	10.840
		Median	36.95	39.19
		Min.	23.5	28.0
		Max.	57.2	57.2
Day 29	SF-12 Score	n	5	7
		Mean	42.33	49.14
		SD	9.066	9.427
		Median	43.68	50.42
		Min.	28.0	30.2
		Max.	52.7	57.2
	Change from Baseline	n	5	6
		Mean	8.98	12.35
		SD	11.120	12.197
		Median	11.22	8.98
		Min.	-9.0	0.0
		Max.	18.0	27.0

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	42.36	54.55
		SD	29.938	24.541
		Median	37.50	50.00
		Min.	0.0	25.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	5	7
		Mean	50.00	69.64
		SD	17.678	18.898
		Median	37.50	75.00
		Min.	37.5	31.3
		Max.	75.0	87.5
	Change from Baseline	n	5	6
		Mean	23.75	19.79
		SD	16.771	24.817
		Median	31.25	18.75
		Min.	0.0	-6.3
		Max.	37.5	56.3

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	9	11
		Mean	43.03	48.82
		SD	14.230	11.664
		Median	40.72	46.66
		Min.	22.9	34.8
		Max.	70.4	70.4
Day 29	SF-12 Score	n	5	7
		Mean	46.66	55.99
		SD	8.400	8.984
		Median	40.72	58.54
		Min.	40.7	37.7
		Max.	58.5	64.5
	Change from Baseline	n	5	6
		Mean	11.29	9.41
		SD	7.972	11.800
		Median	14.85	8.91
		Min.	0.0	-3.0
		Max.	17.8	26.7

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		502	503
Baseline	SF-12 Score	n	383	381
		Mean	55.88	56.69
		SD	33.483	32.815
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	248	231
		Mean	79.54	80.95
		SD	26.752	29.113
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	206	200
		Mean	20.82	24.50
		SD	35.882	37.841
		Median	25.00	25.00
		Min.	-50.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	383	381
		Mean	43.17	43.43
		SD	10.541	10.330
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	248	231
		Mean	50.62	51.06
		SD	8.422	9.165
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	206	200
		Mean	6.55	7.71
		SD	11.296	11.912
		Median	7.87	7.87
		Min.	-15.7	-31.5
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	382	381
		Mean	50.65	52.30
		SD	27.432	28.642
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	248	231
		Mean	77.17	80.68
		SD	24.560	25.740
		Median	75.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	206	200
		Mean	26.64	29.25
		SD	30.312	32.784
		Median	25.00	25.00
		Min.	-50.0	-62.5
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	382	381
		Mean	40.76	41.31
		SD	9.287	9.696
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	248	231
		Mean	49.73	50.92
		SD	8.313	8.713
		Median	49.00	57.46
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	206	200
		Mean	9.02	9.90
		SD	10.260	11.098
		Median	8.46	8.46
		Min.	-16.9	-21.2
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	381	381
		Mean	61.94	60.63
		SD	29.162	30.271
		Median	75.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	248	231
		Mean	85.38	88.64
		SD	22.954	21.824
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	206	200
		Mean	23.18	27.38
		SD	30.137	31.363
		Median	25.00	25.00
		Min.	-50.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	381	381
		Mean	44.00	43.53
		SD	10.521	10.920
		Median	48.71	39.69
		Min.	21.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	248	231
		Mean	52.46	53.63
		SD	8.281	7.874
		Median	57.73	57.73
		Min.	21.7	21.7
		Max.	57.7	57.7
	Change from Baseline	n	206	200
		Mean	8.36	9.88
		SD	10.873	11.315
		Median	9.02	9.02
		Min.	-18.0	-27.1
		Max.	36.1	36.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	383	381
		Mean	55.38	53.78
		SD	28.500	29.434
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	248	231
		Mean	71.17	69.18
		SD	19.981	20.520
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	206	200
		Mean	13.98	13.63
		SD	25.113	32.104
		Median	0.00	0.00
		Min.	-40.0	-100.0
		Max.	85.0	85.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	383	381
		Mean	45.91	45.28
		SD	11.330	11.701
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	248	231
		Mean	52.19	51.40
		SD	7.945	8.159
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
	Change from Baseline	n	206	200
		Mean	5.56	5.42
		SD	9.984	12.763
		Median	0.00	0.00
		Min.	-15.9	-39.8
		Max.	33.8	33.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	382	381
		Mean	36.26	35.96
		SD	28.018	27.857
		Median	25.00	25.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	248	230
		Mean	60.38	66.52
		SD	31.664	33.022
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	206	200
		Mean	25.49	29.38
		SD	32.381	39.104
		Median	25.00	25.00
		Min.	-50.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	382	381
		Mean	43.66	43.54
		SD	11.025	10.962
		Median	39.23	39.23
		Min.	29.4	29.4
		Max.	68.7	68.7
Day 29	SF-12 Score	n	248	230
		Mean	53.15	55.57
		SD	12.459	12.993
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	206	200
		Mean	10.03	11.56
		SD	12.742	15.387
		Median	9.84	9.84
		Min.	-19.7	-39.3
		Max.	39.3	39.3

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	382	381
		Mean	47.58	46.85
		SD	35.573	35.770
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	248	231
		Mean	81.55	85.82
		SD	25.746	25.787
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	206	200
		Mean	32.40	39.63
		SD	38.767	40.434
		Median	25.00	50.00
		Min.	-75.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	382	381
		Mean	38.25	37.99
		SD	12.657	12.727
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	248	231
		Mean	50.34	51.86
		SD	9.159	9.174
		Median	56.90	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	206	200
		Mean	11.53	14.10
		SD	13.792	14.386
		Median	8.90	17.79
		Min.	-26.7	-26.7
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	382	381
		Mean	64.63	66.27
		SD	27.737	29.247
		Median	62.50	62.50
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	248	231
		Mean	83.97	87.72
		SD	23.355	22.661
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	206	200
		Mean	18.63	21.94
		SD	28.417	31.690
		Median	12.50	18.75
		Min.	-75.0	-62.5
		Max.	87.5	100.0

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	382	381
		Mean	41.57	42.26
		SD	11.534	12.162
		Median	40.69	40.69
		Min.	14.7	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	248	231
		Mean	49.62	51.17
		SD	9.711	9.423
		Median	56.28	56.28
		Min.	14.7	14.7
		Max.	56.3	56.3
	Change from Baseline	n	206	200
		Mean	7.75	9.12
		SD	11.817	13.177
		Median	5.20	7.80
		Min.	-31.2	-26.0
		Max.	36.4	41.6

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	382	381
		Mean	57.72	58.73
		SD	22.425	23.910
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	248	231
		Mean	74.70	78.35
		SD	22.353	21.578
		Median	75.00	87.50
		Min.	12.5	12.5
		Max.	100.0	100.0
	Change from Baseline	n	206	200
		Mean	17.05	21.56
		SD	26.128	29.969
		Median	12.50	18.75
		Min.	-37.5	-50.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	382	381
		Mean	44.81	45.27
		SD	10.291	10.972
		Median	41.26	41.26
		Min.	18.3	18.3
		Max.	64.2	64.2
Day 29	SF-12 Score	n	248	231
		Mean	52.60	54.28
		SD	10.258	9.903
		Median	52.74	58.47
		Min.	24.1	24.1
		Max.	64.2	64.2
	Change from Baseline	n	206	200
		Mean	7.83	9.90
		SD	11.991	13.753
		Median	5.74	8.60
		Min.	-17.2	-23.0
		Max.	34.4	45.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	382	381
		Mean	43.60	43.37
		SD	9.168	8.834
		Median	43.93	43.93
		Min.	17.4	20.2
		Max.	62.6	64.6
Day 29	SF-12 Score	n	248	231
		Mean	51.08	51.25
		SD	7.292	8.011
		Median	52.42	53.65
		Min.	22.7	23.5
		Max.	65.3	69.4
	Change from Baseline	n	206	200
		Mean	6.98	7.53
		SD	8.910	9.381
		Median	5.61	7.83
		Min.	-13.3	-19.7
		Max.	35.6	30.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	382	381
		Mean	42.53	42.88
		SD	10.073	10.382
		Median	41.47	41.87
		Min.	13.8	11.0
		Max.	73.0	69.3
Day 29	SF-12 Score	n	248	231
		Mean	51.55	53.64
		SD	9.927	9.010
		Median	53.21	55.60
		Min.	16.0	20.4
		Max.	65.6	66.8
	Change from Baseline	n	206	200
		Mean	9.10	11.24
		SD	11.284	12.556
		Median	7.66	12.34
		Min.	-18.4	-20.6
		Max.	45.3	43.7

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	381	381
		Mean	0.642	0.640
		SD	0.1219	0.1308
		Median	0.618	0.618
		Min.	0.35	0.35
		Max.	1.00	1.00
Day 29	SF-12 Score	n	248	230
		Mean	0.794	0.837
		SD	0.1493	0.1520
		Median	0.797	0.860
		Min.	0.41	0.43
		Max.	1.00	1.00
	Change from Baseline	n	206	200
		Mean	0.154	0.197
		SD	0.1618	0.1852
		Median	0.123	0.203
		Min.	-0.26	-0.31
		Max.	0.52	0.66

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	382	381
		Mean	48.76	49.38
		SD	26.277	27.807
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	248	231
		Mean	78.28	82.60
		SD	23.385	23.800
		Median	87.50	93.75
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	206	200
		Mean	29.34	34.03
		SD	28.483	30.993
		Median	25.00	37.50
		Min.	-56.3	-56.3
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	382	381
		Mean	38.74	38.97
		SD	9.441	9.991
		Median	39.19	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 29	SF-12 Score	n	248	231
		Mean	49.35	50.91
		SD	8.403	8.552
		Median	52.66	54.91
		Min.	21.2	21.2
		Max.	57.2	57.2
	Change from Baseline	n	206	200
		Mean	10.54	12.23
		SD	10.234	11.136
		Median	8.99	13.48
		Min.	-20.2	-20.2
		Max.	35.9	35.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	382	381
		Mean	40.61	40.62
		SD	24.279	24.651
		Median	43.75	43.75
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	248	231
		Mean	67.36	72.68
		SD	25.497	25.146
		Median	68.75	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	206	200
		Mean	28.09	32.72
		SD	25.970	28.965
		Median	25.00	37.50
		Min.	-50.0	-50.0
		Max.	93.8	100.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	382	381
		Mean	42.19	42.20
		SD	11.541	11.718
		Median	43.69	43.69
		Min.	22.9	22.9
		Max.	70.4	70.4
Day 29	SF-12 Score	n	248	231
		Mean	54.91	57.44
		SD	12.118	11.951
		Median	55.57	58.54
		Min.	22.9	22.9
		Max.	70.4	70.4
	Change from Baseline	n	206	200
		Mean	13.35	15.55
		SD	12.344	13.767
		Median	11.89	17.82
		Min.	-23.8	-23.8
		Max.	44.6	47.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		12	11
Baseline	SF-12 Score	n	7	7
		Mean	64.29	75.00
		SD	34.932	43.301
		Median	50.00	100.00
		Min.	25.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	4	3
		Mean	75.00	66.67
		SD	20.412	14.434
		Median	75.00	75.00
		Min.	50.0	50.0
		Max.	100.0	75.0
	Change from Baseline	n	4	3
		Mean	0.00	-33.33
		SD	20.412	14.434
		Median	0.00	-25.00
		Min.	-25.0	-50.0
		Max.	25.0	-25.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	45.82	49.19
		SD	10.997	13.631
		Median	41.32	57.06
		Min.	33.5	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	4	3
		Mean	49.19	46.57
		SD	6.426	4.544
		Median	49.19	49.19
		Min.	41.3	41.3
		Max.	57.1	49.2
	Change from Baseline	n	4	3
		Mean	-0.00	-10.49
		SD	6.426	4.544
		Median	0.00	-7.87
		Min.	-7.9	-15.7
		Max.	7.9	-7.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	48.21	64.29
		SD	30.981	29.252
		Median	50.00	62.50
		Min.	12.5	25.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	4	3
		Mean	78.13	83.33
		SD	25.769	19.094
		Median	81.25	87.50
		Min.	50.0	62.5
		Max.	100.0	100.0
	Change from Baseline	n	4	3
		Mean	37.50	8.33
		SD	10.206	26.021
		Median	37.50	0.00
		Min.	25.0	-12.5
		Max.	50.0	37.5

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	39.93	45.37
		SD	10.488	9.902
		Median	40.54	44.77
		Min.	27.8	32.1
		Max.	57.5	57.5
Day 29	SF-12 Score	n	4	3
		Mean	50.06	51.82
		SD	8.720	6.461
		Median	51.12	53.23
		Min.	40.5	44.8
		Max.	57.5	57.5
	Change from Baseline	n	4	3
		Mean	12.70	2.82
		SD	3.454	8.805
		Median	12.70	0.00
		Min.	8.5	-4.2
		Max.	16.9	12.7

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	67.86	71.43
		SD	34.503	22.493
		Median	75.00	75.00
		Min.	25.0	50.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	4	3
		Mean	100.00	100.00
		SD	0.000	0.000
		Median	100.00	100.00
		Min.	100.0	100.0
		Max.	100.0	100.0
	Change from Baseline	n	4	3
		Mean	37.50	33.33
		SD	32.275	28.868
		Median	37.50	50.00
		Min.	0.0	0.0
		Max.	75.0	50.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	46.13	47.42
		SD	12.449	8.116
		Median	48.71	48.71
		Min.	30.7	39.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	4	3
		Mean	57.73	57.73
		SD	0.000	0.000
		Median	57.73	57.73
		Min.	57.7	57.7
		Max.	57.7	57.7
	Change from Baseline	n	4	3
		Mean	13.53	12.03
		SD	11.645	10.415
		Median	13.53	18.04
		Min.	0.0	0.0
		Max.	27.1	18.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	70.71	66.43
		SD	13.363	26.254
		Median	60.00	60.00
		Min.	60.0	25.0
		Max.	85.0	100.0
Day 29	SF-12 Score	n	4	3
		Mean	86.25	48.33
		SD	18.875	20.207
		Median	92.50	60.00
		Min.	60.0	25.0
		Max.	100.0	60.0
	Change from Baseline	n	4	3
		Mean	13.75	0.00
		SD	10.308	0.000
		Median	15.00	0.00
		Min.	0.0	0.0
		Max.	25.0	0.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	52.01	50.31
		SD	5.313	10.440
		Median	47.75	47.75
		Min.	47.8	33.8
		Max.	57.7	63.7
Day 29	SF-12 Score	n	4	3
		Mean	58.19	43.11
		SD	7.507	8.031
		Median	60.68	47.75
		Min.	47.8	33.8
		Max.	63.7	47.8
	Change from Baseline	n	4	3
		Mean	5.47	0.00
		SD	4.099	0.000
		Median	5.97	0.00
		Min.	0.0	0.0
		Max.	9.9	0.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	46.43	28.57
		SD	17.252	17.252
		Median	50.00	25.00
		Min.	25.0	0.0
		Max.	75.0	50.0
Day 29	SF-12 Score	n	4	3
		Mean	68.75	50.00
		SD	23.936	25.000
		Median	62.50	50.00
		Min.	50.0	25.0
		Max.	100.0	75.0
	Change from Baseline	n	4	3
		Mean	25.00	16.67
		SD	20.412	38.188
		Median	25.00	25.00
		Min.	0.0	-25.0
		Max.	50.0	50.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	47.66	40.64
		SD	6.787	6.790
		Median	49.07	39.23
		Min.	39.2	29.4
		Max.	58.9	49.1
Day 29	SF-12 Score	n	4	3
		Mean	56.45	49.07
		SD	9.416	9.835
		Median	53.99	49.07
		Min.	49.1	39.2
		Max.	68.7	58.9
	Change from Baseline	n	4	3
		Mean	9.84	6.56
		SD	8.030	15.030
		Median	9.84	9.83
		Min.	0.0	-9.8
		Max.	19.7	19.7

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	35.71	42.86
		SD	45.316	47.246
		Median	25.00	25.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	4	3
		Mean	62.50	91.67
		SD	43.301	14.434
		Median	62.50	100.00
		Min.	25.0	75.0
		Max.	100.0	100.0
	Change from Baseline	n	4	3
		Mean	56.25	0.00
		SD	51.539	0.000
		Median	62.50	0.00
		Min.	0.0	0.0
		Max.	100.0	0.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	34.03	36.57
		SD	16.123	16.810
		Median	30.22	30.22
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	4	3
		Mean	43.56	53.94
		SD	15.404	5.133
		Median	43.56	56.90
		Min.	30.2	48.0
		Max.	56.9	56.9
	Change from Baseline	n	4	3
		Mean	20.02	0.00
		SD	18.337	0.000
		Median	22.24	0.00
		Min.	0.0	0.0
		Max.	35.6	0.0

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	80.36	82.14
		SD	28.738	23.780
		Median	100.00	100.00
		Min.	25.0	50.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	4	3
		Mean	93.75	83.33
		SD	12.500	14.434
		Median	100.00	75.00
		Min.	75.0	75.0
		Max.	100.0	100.0
	Change from Baseline	n	4	3
		Mean	0.00	0.00
		SD	0.000	25.000
		Median	0.00	0.00
		Min.	0.0	-25.0
		Max.	0.0	25.0

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	48.11	48.86
		SD	11.951	9.887
		Median	56.28	56.28
		Min.	25.1	35.5
		Max.	56.3	56.3
Day 29	SF-12 Score	n	4	3
		Mean	53.68	49.35
		SD	5.195	5.999
		Median	56.28	45.89
		Min.	45.9	45.9
		Max.	56.3	56.3
	Change from Baseline	n	4	3
		Mean	0.00	0.00
		SD	0.000	10.395
		Median	0.00	0.00
		Min.	0.0	-10.4
		Max.	0.0	10.4

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	82.14	67.86
		SD	6.682	22.658
		Median	87.50	75.00
		Min.	75.0	25.0
		Max.	87.5	87.5
Day 29	SF-12 Score	n	4	3
		Mean	84.38	70.83
		SD	11.968	14.434
		Median	81.25	62.50
		Min.	75.0	62.5
		Max.	100.0	87.5
	Change from Baseline	n	4	3
		Mean	3.13	0.00
		SD	11.968	12.500
		Median	6.25	0.00
		Min.	-12.5	-12.5
		Max.	12.5	12.5

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	56.01	49.46
		SD	3.063	10.399
		Median	58.47	52.74
		Min.	52.7	29.8
		Max.	58.5	58.5
Day 29	SF-12 Score	n	4	3
		Mean	57.04	50.82
		SD	5.490	6.622
		Median	55.61	47.00
		Min.	52.7	47.0
		Max.	64.2	58.5
	Change from Baseline	n	4	3
		Mean	1.43	0.00
		SD	5.489	5.740
		Median	2.86	0.00
		Min.	-5.7	-5.7
		Max.	5.7	5.7

Note: SF-12 was scheduled for the Expansion phase only.

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Physical Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	43.05	47.46
		SD	8.246	10.614
		Median	41.67	44.29
		Min.	32.2	33.2
		Max.	55.6	62.1
Day 29	SF-12 Score	n	4	3
		Mean	52.15	49.80
		SD	5.924	5.460
		Median	52.79	49.81
		Min.	45.2	44.3
		Max.	57.8	55.3
	Change from Baseline	n	4	3
		Mean	9.93	0.55
		SD	3.000	7.043
		Median	10.01	1.39
		Min.	6.7	-6.9
		Max.	13.0	7.1

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Mental Component Summary

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	49.81	44.43
		SD	4.650	10.075
		Median	48.73	43.87
		Min.	43.2	31.7
		Max.	58.3	59.1
Day 29	SF-12 Score	n	4	3
		Mean	54.10	50.88
		SD	5.888	7.975
		Median	54.60	48.14
		Min.	46.5	44.6
		Max.	60.8	59.9
	Change from Baseline	n	4	3
		Mean	5.42	2.44
		SD	6.050	3.818
		Median	5.25	0.80
		Min.	-1.8	-0.3
		Max.	13.0	6.8

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Health Utility Index

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	0.688	0.656
		SD	0.0976	0.0898
		Median	0.689	0.644
		Min.	0.55	0.54
		Max.	0.86	0.82
Day 29	SF-12 Score	n	4	3
		Mean	0.802	0.788
		SD	0.1067	0.1311
		Median	0.851	0.782
		Min.	0.64	0.66
		Max.	0.86	0.92
	Change from Baseline	n	4	3
		Mean	0.154	0.078
		SD	0.0521	0.0240
		Median	0.158	0.070
		Min.	0.09	0.06
		Max.	0.21	0.11

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	52.68	59.82
		SD	28.609	26.481
		Median	43.75	56.25
		Min.	18.8	25.0
		Max.	100.0	93.8
Day 29	SF-12 Score	n	4	3
		Mean	85.94	83.33
		SD	17.952	13.010
		Median	90.63	87.50
		Min.	62.5	68.8
		Max.	100.0	93.8
	Change from Baseline	n	4	3
		Mean	43.75	8.33
		SD	8.839	26.021
		Median	40.63	0.00
		Min.	37.5	-12.5
		Max.	56.3	37.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	40.15	42.72
		SD	10.279	9.514
		Median	36.95	41.44
		Min.	28.0	30.2
		Max.	57.2	54.9
Day 29	SF-12 Score	n	4	3
		Mean	52.11	51.17
		SD	6.453	4.673
		Median	53.79	52.66
		Min.	43.7	45.9
		Max.	57.2	54.9
	Change from Baseline	n	4	3
		Mean	15.72	2.99
		SD	3.175	9.347
		Median	14.60	0.00
		Min.	13.5	-4.5
		Max.	20.2	13.5

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	49.11	36.61
		SD	5.623	13.223
		Median	50.00	31.25
		Min.	37.5	25.0
		Max.	56.3	56.3
Day 29	SF-12 Score	n	4	3
		Mean	68.75	58.33
		SD	21.041	28.183
		Median	59.38	56.25
		Min.	56.3	31.3
		Max.	100.0	87.5
	Change from Baseline	n	4	3
		Mean	21.88	14.58
		SD	19.432	14.434
		Median	15.63	6.25
		Min.	6.3	6.3
		Max.	50.0	31.3

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.77
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	SF-12 Score	n	7	7
		Mean	46.24	40.29
		SD	2.672	6.289
		Median	46.66	37.74
		Min.	40.7	34.8
		Max.	49.6	49.6
Day 29	SF-12 Score	n	4	3
		Mean	55.57	50.62
		SD	9.999	13.397
		Median	51.12	49.63
		Min.	49.6	37.7
		Max.	70.4	64.5
	Change from Baseline	n	4	3
		Mean	10.40	6.93
		SD	9.234	6.859
		Median	7.43	2.97
		Min.	3.0	3.0
		Max.	23.8	14.9

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	15	14
n	5	6
LS Mean (SE)	62.45 (11.999)	83.78 (10.965)
95% C.I.	(38.86, 86.04)	(62.23, 105.33)
LS Mean Change from Baseline (SE)	3.34 (11.999)	24.67 (10.965)
95% C.I.	(-20.24, 26.93)	(3.12, 46.23)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		21.33 (16.237)
95% C.I.		(-10.59, 53.25)
p-value		0.190
Corrected Hedge’s g (SE) [1]		0.73 (0.625)
95% C.I.		(-0.50, 1.95)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Role Physical (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	5	6
LS Mean (SE)	56.02 (10.881)	74.32 (9.921)
95% C.I.	(34.63, 77.41)	(54.82, 93.82)
LS Mean Change from Baseline (SE)	4.70 (10.881)	22.99 (9.921)
95% C.I.	(-16.69, 26.09)	(3.49, 42.49)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		18.29 (14.715)
95% C.I.		(-10.63, 47.22)
p-value		0.215
Corrected Hedge’s g (SE) [1]		0.69 (0.623)
95% C.I.		(-0.53, 1.91)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	5	6
LS Mean (SE)	88.28 (9.524)	88.37 (8.692)
95% C.I.	(69.56, 107.00)	(71.29, 105.46)
LS Mean Change from Baseline (SE)	26.02 (9.524)	26.11 (8.692)
95% C.I.	(7.29, 44.74)	(9.02, 43.19)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.09 (12.897)
95% C.I.		(-25.26, 25.45)
p-value		0.994
Corrected Hedge’s g (SE) [1]		0.00 (0.606)
95% C.I.		(-1.18, 1.19)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: General Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	5	6
LS Mean (SE)	41.45 (8.655)	63.07 (7.908)
95% C.I.	(24.44, 58.46)	(47.53, 78.62)
LS Mean Change from Baseline (SE)	-14.99 (8.655)	6.64 (7.908)
95% C.I.	(-32.00, 2.03)	(-8.91, 22.18)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		21.62 (11.741)
95% C.I.		(-1.45, 44.70)
p-value		0.066
Corrected Hedge’s g (SE) [1]		1.02 (0.643)
95% C.I.		(-0.24, 2.28)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Vitality (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	5	6
LS Mean (SE)	40.77 (13.807)	61.41 (12.660)
95% C.I.	(13.63, 67.91)	(36.52, 86.29)
LS Mean Change from Baseline (SE)	4.63 (13.807)	25.26 (12.660)
95% C.I.	(-22.51, 31.77)	(0.38, 50.15)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		20.63 (18.799)
95% C.I.		(-16.32, 57.59)
p-value		0.273
Corrected Hedge’s g (SE) [1]		0.61 (0.619)
95% C.I.		(-0.60, 1.82)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	5	6
LS Mean (SE)	60.02 (11.673)	88.82 (10.590)
95% C.I.	(37.07, 82.97)	(68.01, 109.64)
LS Mean Change from Baseline (SE)	12.67 (11.673)	41.48 (10.590)
95% C.I.	(-10.27, 35.62)	(20.66, 62.29)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		28.80 (15.730)
95% C.I.		(-2.12, 59.72)
p-value		0.068
Corrected Hedge’s g (SE) [1]		1.01 (0.643)
95% C.I.		(-0.25, 2.27)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	5	6
LS Mean (SE)	71.64 (9.763)	88.92 (8.941)
95% C.I.	(52.45, 90.83)	(71.34, 106.49)
LS Mean Change from Baseline (SE)	4.98 (9.763)	22.26 (8.941)
95% C.I.	(-14.21, 24.17)	(4.68, 39.83)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		17.28 (13.231)
95% C.I.		(-8.73, 43.29)
p-value		0.192
Corrected Hedge’s g (SE) [1]		0.72 (0.625)
95% C.I.		(-0.50, 1.95)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Mental Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	5	6
LS Mean (SE)	62.85 (9.474)	74.77 (8.654)
95% C.I.	(44.22, 81.47)	(57.76, 91.79)
LS Mean Change from Baseline (SE)	4.27 (9.474)	16.20 (8.654)
95% C.I.	(-14.35, 22.89)	(-0.82, 33.21)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		11.93 (12.808)
95% C.I.		(-13.25, 37.10)
p-value		0.352
Corrected Hedge’s g (SE) [1]		0.51 (0.615)
95% C.I.		(-0.69, 1.72)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Physical Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	5	6
LS Mean (SE)	45.62 (3.155)	50.77 (2.882)
95% C.I.	(39.42, 51.82)	(45.10, 56.43)
LS Mean Change from Baseline (SE)	1.61 (3.155)	6.76 (2.882)
95% C.I.	(-4.59, 7.81)	(1.10, 12.43)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		5.15 (4.273)
95% C.I.		(-3.25, 13.55)
p-value		0.229
Corrected Hedge’s g (SE) [1]		0.67 (0.622)
95% C.I.		(-0.55, 1.89)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Mental Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	5	6
LS Mean (SE)	45.12 (4.091)	53.27 (3.747)
95% C.I.	(37.08, 53.16)	(45.91, 60.64)
LS Mean Change from Baseline (SE)	2.35 (4.091)	10.50 (3.747)
95% C.I.	(-5.69, 10.39)	(3.14, 17.87)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		8.15 (5.554)
95% C.I.		(-2.77, 19.07)
p-value		0.143
Corrected Hedge’s g (SE) [1]		0.81 (0.630)
95% C.I.		(-0.42, 2.05)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Health Utility Index

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	5	6
LS Mean (SE)	0.69 (0.065)	0.81 (0.060)
95% C.I.	(0.56, 0.81)	(0.69, 0.93)
LS Mean Change from Baseline (SE)	0.04 (0.065)	0.17 (0.060)
95% C.I.	(-0.09, 0.17)	(0.05, 0.28)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.13 (0.088)
95% C.I.		(-0.05, 0.30)
p-value		0.158
Corrected Hedge’s g (SE) [1]		0.78 (0.628)
95% C.I.		(-0.45, 2.01)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	5	6
LS Mean (SE)	62.80 (10.143)	78.75 (9.244)
95% C.I.	(42.86, 82.74)	(60.58, 96.92)
LS Mean Change from Baseline (SE)	13.80 (10.143)	29.76 (9.244)
95% C.I.	(-6.13, 33.74)	(11.59, 47.93)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		15.95 (13.711)
95% C.I.		(-11.00, 42.90)
p-value		0.245
Corrected Hedge’s g (SE) [1]		0.64 (0.621)
95% C.I.		(-0.57, 1.86)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: Europe
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	5	6
LS Mean (SE)	55.56 (10.497)	65.72 (9.576)
95% C.I.	(34.92, 76.19)	(46.90, 84.54)
LS Mean Change from Baseline (SE)	15.60 (10.497)	25.76 (9.576)
95% C.I.	(-5.04, 36.23)	(6.94, 44.58)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		10.16 (14.231)
95% C.I.		(-17.81, 38.14)
p-value		0.476
Corrected Hedge’s g (SE) [1]		0.40 (0.611)
95% C.I.		(-0.80, 1.59)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	502	503
n	206	200
LS Mean (SE)	81.08 (1.869)	81.13 (1.900)
95% C.I.	(77.41, 84.75)	(77.40, 84.87)
LS Mean Change from Baseline (SE)	21.97 (1.869)	22.03 (1.900)
95% C.I.	(18.30, 25.65)	(18.29, 25.76)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.05 (2.669)
95% C.I.		(-5.19, 5.30)
p-value		0.984
Corrected Hedge’s g (SE) [1]		0.00 (0.099)
95% C.I.		(-0.19, 0.20)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Role Physical (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	206	200
LS Mean (SE)	78.51 (1.693)	80.29 (1.718)
95% C.I.	(75.19, 81.84)	(76.91, 83.66)
LS Mean Change from Baseline (SE)	27.19 (1.693)	28.96 (1.718)
95% C.I.	(23.86, 30.51)	(25.58, 32.34)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		1.77 (2.412)
95% C.I.		(-2.97, 6.51)
p-value		0.463
Corrected Hedge’s g (SE) [1]		0.07 (0.099)
95% C.I.		(-0.12, 0.27)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	206	200
LS Mean (SE)	86.29 (1.484)	88.66 (1.506)
95% C.I.	(83.37, 89.20)	(85.70, 91.62)
LS Mean Change from Baseline (SE)	24.02 (1.484)	26.39 (1.506)
95% C.I.	(21.11, 26.94)	(23.43, 29.35)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.37 (2.115)
95% C.I.		(-1.79, 6.53)
p-value		0.263
Corrected Hedge’s g (SE) [1]		0.11 (0.099)
95% C.I.		(-0.08, 0.31)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: General Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	206	200
LS Mean (SE)	71.45 (1.348)	68.94 (1.368)
95% C.I.	(68.81, 74.10)	(66.25, 71.63)
LS Mean Change from Baseline (SE)	15.02 (1.348)	12.50 (1.368)
95% C.I.	(12.37, 17.67)	(9.81, 15.19)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.51 (1.922)
95% C.I.		(-6.29, 1.26)
p-value		0.192
Corrected Hedge’s g (SE) [1]		-0.13 (0.099)
95% C.I.		(-0.32, 0.07)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Vitality (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	206	200
LS Mean (SE)	61.02 (2.147)	65.83 (2.179)
95% C.I.	(56.80, 65.24)	(61.55, 70.11)
LS Mean Change from Baseline (SE)	24.88 (2.147)	29.68 (2.179)
95% C.I.	(20.65, 29.10)	(25.40, 33.97)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.81 (3.060)
95% C.I.		(-1.21, 10.82)
p-value		0.117
Corrected Hedge’s g (SE) [1]		0.16 (0.099)
95% C.I.		(-0.04, 0.35)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	206	200
LS Mean (SE)	81.84 (1.808)	86.02 (1.834)
95% C.I.	(78.28, 85.39)	(82.42, 89.63)
LS Mean Change from Baseline (SE)	34.49 (1.808)	38.68 (1.834)
95% C.I.	(30.93, 38.04)	(35.07, 42.28)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.19 (2.577)
95% C.I.		(-0.88, 9.25)
p-value		0.105
Corrected Hedge’s g (SE) [1]		0.16 (0.099)
95% C.I.		(-0.03, 0.36)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	206	200
LS Mean (SE)	84.90 (1.521)	87.92 (1.544)
95% C.I.	(81.91, 87.89)	(84.89, 90.96)
LS Mean Change from Baseline (SE)	18.25 (1.521)	21.26 (1.544)
95% C.I.	(15.26, 21.24)	(18.23, 24.30)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.02 (2.167)
95% C.I.		(-1.24, 7.28)
p-value		0.164
Corrected Hedge’s g (SE) [1]		0.14 (0.099)
95% C.I.		(-0.06, 0.33)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Mental Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	206	200
LS Mean (SE)	75.22 (1.474)	79.52 (1.496)
95% C.I.	(72.32, 78.11)	(76.58, 82.46)
LS Mean Change from Baseline (SE)	16.64 (1.474)	20.94 (1.496)
95% C.I.	(13.74, 19.54)	(18.00, 23.88)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.30 (2.100)
95% C.I.		(0.17, 8.43)
p-value		0.041
Corrected Hedge’s g (SE) [1]		0.20 (0.100)
95% C.I.		(0.01, 0.40)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Physical Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	206	200
LS Mean (SE)	51.40 (0.492)	51.13 (0.499)
95% C.I.	(50.43, 52.37)	(50.14, 52.11)
LS Mean Change from Baseline (SE)	7.39 (0.492)	7.12 (0.499)
95% C.I.	(6.42, 8.36)	(6.14, 8.10)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.27 (0.702)
95% C.I.		(-1.65, 1.11)
p-value		0.697
Corrected Hedge’s g (SE) [1]		-0.04 (0.099)
95% C.I.		(-0.23, 0.16)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Mental Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	206	200
LS Mean (SE)	51.69 (0.637)	53.94 (0.647)
95% C.I.	(50.43, 52.94)	(52.67, 55.21)
LS Mean Change from Baseline (SE)	8.91 (0.637)	11.17 (0.647)
95% C.I.	(7.66, 10.17)	(9.90, 12.44)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.25 (0.908)
95% C.I.		(0.47, 4.04)
p-value		0.013
Corrected Hedge’s g (SE) [1]		0.25 (0.100)
95% C.I.		(0.05, 0.44)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Health Utility Index

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	206	200
LS Mean (SE)	0.80 (0.010)	0.84 (0.010)
95% C.I.	(0.78, 0.82)	(0.82, 0.86)
LS Mean Change from Baseline (SE)	0.16 (0.010)	0.19 (0.010)
95% C.I.	(0.14, 0.18)	(0.17, 0.21)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.04 (0.014)
95% C.I.		(0.01, 0.06)
p-value		0.013
Corrected Hedge’s g (SE) [1]		0.25 (0.100)
95% C.I.		(0.05, 0.44)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	206	200
LS Mean (SE)	79.23 (1.578)	82.34 (1.601)
95% C.I.	(76.13, 82.33)	(79.20, 85.49)
LS Mean Change from Baseline (SE)	30.23 (1.578)	33.34 (1.601)
95% C.I.	(27.13, 33.33)	(30.20, 36.49)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.11 (2.249)
95% C.I.		(-1.31, 7.53)
p-value		0.167
Corrected Hedge’s g (SE) [1]		0.14 (0.099)
95% C.I.		(-0.06, 0.33)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: North America
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	206	200
LS Mean (SE)	68.07 (1.632)	72.57 (1.656)
95% C.I.	(64.86, 71.28)	(69.32, 75.83)
LS Mean Change from Baseline (SE)	28.11 (1.632)	32.61 (1.656)
95% C.I.	(24.90, 31.32)	(29.36, 35.87)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.50 (2.325)
95% C.I.		(-0.07, 9.07)
p-value		0.054
Corrected Hedge’s g (SE) [1]		0.19 (0.099)
95% C.I.		(0.00, 0.39)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

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Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	12	11
n	4	3
LS Mean (SE)	71.28 (13.422)	57.09 (15.568)
95% C.I.	(44.90, 97.66)	(26.49, 87.69)
LS Mean Change from Baseline (SE)	12.17 (13.422)	-2.01 (15.568)
95% C.I.	(-14.21, 38.56)	(-32.61, 28.59)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-14.19 (20.503)
95% C.I.		(-54.49, 26.12)
p-value		0.489
Corrected Hedge’s g (SE) [1]		-0.44 (0.773)
95% C.I.		(-1.96, 1.07)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Role Physical (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	4	3
LS Mean (SE)	80.85 (12.156)	77.30 (14.064)
95% C.I.	(56.96, 104.75)	(49.65, 104.95)
LS Mean Change from Baseline (SE)	29.53 (12.156)	25.97 (14.064)
95% C.I.	(5.63, 53.42)	(-1.67, 53.62)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-3.55 (18.616)
95% C.I.		(-40.14, 33.04)
p-value		0.849
Corrected Hedge’s g (SE) [1]		-0.12 (0.764)
95% C.I.		(-1.62, 1.38)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	4	3
LS Mean (SE)	99.95 (10.644)	99.02 (12.291)
95% C.I.	(79.03, 120.87)	(74.86, 123.18)
LS Mean Change from Baseline (SE)	37.68 (10.644)	36.76 (12.291)
95% C.I.	(16.76, 58.61)	(12.60, 60.92)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.93 (16.259)
95% C.I.		(-32.89, 31.03)
p-value		0.955
Corrected Hedge’s g (SE) [1]		-0.04 (0.764)
95% C.I.		(-1.53, 1.46)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: General Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	4	3
LS Mean (SE)	82.71 (9.683)	50.12 (11.165)
95% C.I.	(63.67, 101.74)	(28.17, 72.07)
LS Mean Change from Baseline (SE)	26.27 (9.683)	-6.32 (11.165)
95% C.I.	(7.24, 45.30)	(-28.26, 15.63)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-32.59 (14.790)
95% C.I.		(-61.66, -3.51)
p-value		0.028
Corrected Hedge’s g (SE) [1]		-1.42 (0.853)
95% C.I.		(-3.09, 0.25)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Vitality (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	4	3
LS Mean (SE)	66.03 (15.411)	51.01 (17.789)
95% C.I.	(35.74, 96.32)	(16.04, 85.97)
LS Mean Change from Baseline (SE)	29.89 (15.411)	14.86 (17.789)
95% C.I.	(-0.41, 60.18)	(-20.11, 49.83)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-15.02 (23.539)
95% C.I.		(-61.29, 31.25)
p-value		0.524
Corrected Hedge’s g (SE) [1]		-0.41 (0.772)
95% C.I.		(-1.92, 1.10)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	4	3
LS Mean (SE)	68.02 (13.048)	85.71 (15.054)
95% C.I.	(42.38, 93.67)	(56.12, 115.30)
LS Mean Change from Baseline (SE)	20.68 (13.048)	38.36 (15.054)
95% C.I.	(-4.97, 46.33)	(8.77, 67.95)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		17.69 (20.042)
95% C.I.		(-21.71, 57.08)
p-value		0.378
Corrected Hedge’s g (SE) [1]		0.57 (0.779)
95% C.I.		(-0.96, 2.10)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	4	3
LS Mean (SE)	86.77 (10.965)	79.04 (12.619)
95% C.I.	(65.21, 108.32)	(54.23, 103.84)
LS Mean Change from Baseline (SE)	20.11 (10.965)	12.38 (12.619)
95% C.I.	(-1.44, 41.66)	(-12.43, 37.18)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-7.73 (16.676)
95% C.I.		(-40.51, 25.05)
p-value		0.643
Corrected Hedge’s g (SE) [1]		-0.30 (0.768)
95% C.I.		(-1.80, 1.21)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Mental Health (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	4	3
LS Mean (SE)	80.10 (10.629)	68.52 (12.225)
95% C.I.	(59.21, 101.00)	(44.49, 92.56)
LS Mean Change from Baseline (SE)	21.52 (10.629)	9.95 (12.225)
95% C.I.	(0.63, 42.42)	(-14.09, 33.98)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-11.58 (16.162)
95% C.I.		(-43.35, 20.19)
p-value		0.474
Corrected Hedge’s g (SE) [1]		-0.46 (0.774)
95% C.I.		(-1.98, 1.06)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Physical Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	4	3
LS Mean (SE)	52.74 (3.528)	48.08 (4.078)
95% C.I.	(45.80, 59.67)	(40.06, 56.09)
LS Mean Change from Baseline (SE)	8.73 (3.528)	4.07 (4.078)
95% C.I.	(1.79, 15.66)	(-3.95, 12.09)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-4.66 (5.395)
95% C.I.		(-15.27, 5.94)
p-value		0.388
Corrected Hedge’s g (SE) [1]		-0.56 (0.778)
95% C.I.		(-2.08, 0.97)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Mental Component Summary

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	4	3
LS Mean (SE)	52.65 (4.580)	49.48 (5.286)
95% C.I.	(43.64, 61.65)	(39.09, 59.87)
LS Mean Change from Baseline (SE)	9.87 (4.580)	6.71 (5.286)
95% C.I.	(0.87, 18.88)	(-3.68, 17.10)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-3.16 (6.985)
95% C.I.		(-16.89, 10.57)
p-value		0.651
Corrected Hedge’s g (SE) [1]		-0.29 (0.768)
95% C.I.		(-1.80, 1.21)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Health Utility Index

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	4	3
LS Mean (SE)	0.80 (0.073)	0.77 (0.084)
95% C.I.	(0.66, 0.94)	(0.61, 0.94)
LS Mean Change from Baseline (SE)	0.16 (0.073)	0.13 (0.084)
95% C.I.	(0.01, 0.30)	(-0.04, 0.29)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.03 (0.111)
95% C.I.		(-0.25, 0.19)
p-value		0.800
Corrected Hedge’s g (SE) [1]		-0.16 (0.765)
95% C.I.		(-1.66, 1.34)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	4	3
LS Mean (SE)	87.75 (11.321)	76.43 (13.114)
95% C.I.	(65.49, 110.00)	(50.65, 102.20)
LS Mean Change from Baseline (SE)	38.75 (11.321)	27.43 (13.114)
95% C.I.	(16.50, 61.00)	(1.65, 53.21)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-11.32 (17.342)
95% C.I.		(-45.41, 22.77)
p-value		0.514
Corrected Hedge’s g (SE) [1]		-0.42 (0.772)
95% C.I.		(-1.93, 1.09)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.78
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Region

Region: South America
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	4	3
LS Mean (SE)	65.95 (11.717)	56.80 (13.526)
95% C.I.	(42.92, 88.98)	(30.21, 83.38)
LS Mean Change from Baseline (SE)	25.99 (11.717)	16.84 (13.526)
95% C.I.	(2.95, 49.02)	(-9.75, 43.42)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-9.15 (17.892)
95% C.I.		(-44.32, 26.02)
p-value		0.609
Corrected Hedge’s g (SE) [1]		-0.33 (0.769)
95% C.I.		(-1.84, 1.18)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 24.79
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Region - GBA Approach

Region: Europe
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	15	14
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	1 (7%)	1 (7%)
Non-responder	4 (27%)	5 (36%)
Missing [1]	10 (67%)	8 (57%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.93
95% C.I.		(0.05, 16.42)
p-value		0.960
Risk Difference (%) [3]		-0.48
95% C.I.		(-18.95, 18.00)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

PPD

Table 24.79
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Region - GBA Approach

Region: North America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	502	503
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	90 (18%)	111 (22%)
Non-responder	116 (23%)	89 (18%)
Missing [1]	296 (59%)	303 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.77
95% C.I.		(0.57, 1.05)
p-value		0.102
Risk Difference (%) [3]		-4.14
95% C.I.		(-9.08, 0.80)
p-value		0.115

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

PPD

Table 24.79
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Region - GBA Approach

Region: South America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	12	11
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	1 (8%)	0
Non-responder	3 (25%)	3 (27%)
Missing [1]	8 (67%)	8 (73%)
VIR-7831 500 mg vs. Placebo:		
Risk Difference (%) [3]		8.33
95% C.I.		(-7.30, 23.97)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.80
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Region - GBA Approach

Region: Europe
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	15	14
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	1 (7%)	3 (21%)
Non-responder	4 (27%)	3 (21%)
Missing [1]	10 (67%)	8 (57%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.26
95% C.I.		(0.02, 2.88)
p-value		0.274
Risk Difference (%) [3]		-14.76
95% C.I.		(-39.69, 10.16)
p-value		0.330

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

PPD

Table 24.80
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Region - GBA Approach

Region: North America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	502	503
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	80 (16%)	93 (18%)
Non-responder	126 (25%)	107 (21%)
Missing [1]	296 (59%)	303 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.84
95% C.I.		(0.60, 1.16)
p-value		0.285
Risk Difference (%) [3]		-2.55
95% C.I.		(-7.22, 2.11)
p-value		0.317

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

PPD

Table 24.80
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Region - GBA Approach

Region: South America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	12	11
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	2 (17%)	0
Non-responder	2 (17%)	3 (27%)
Missing [1]	8 (67%)	8 (73%)
VIR-7831 500 mg vs. Placebo:		
Risk Difference (%) [3]		16.67
95% C.I.		(-4.42, 37.75)
p-value		0.479

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).

PPD

Table 24.81
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Region - QualityMetric Approach

Region: Europe
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	15	14
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	1 (7%)	2 (14%)
Non-responder	4 (27%)	4 (29%)
Missing [1]	10 (67%)	8 (57%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.43
95% C.I.		(0.03, 5.33)
p-value		0.511
Risk Difference (%) [3]		-7.62
95% C.I.		(-29.88, 14.64)
p-value		0.598

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

PPD

Table 24.81
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Region - QualityMetric Approach

Region: North America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	502	503
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	111 (22%)	125 (25%)
Non-responder	95 (19%)	75 (15%)
Missing [1]	296 (59%)	303 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.86
95% C.I.		(0.64, 1.15)
p-value		0.306
Risk Difference (%) [3]		-2.74
95% C.I.		(-7.98, 2.50)
p-value		0.334

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

PPD

Table 24.81
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Region - QualityMetric Approach

Region: South America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	12	11
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	1 (8%)	0
Non-responder	3 (25%)	3 (27%)
Missing [1]	8 (67%)	8 (73%)
VIR-7831 500 mg vs. Placebo:		
Risk Difference (%) [3]		8.33
95% C.I.		(-7.30, 23.97)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).

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Population: Intent-to-Treat Data as of 27APR2021

Table 24.82
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Region - QualityMetric Approach

Region: Europe
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	15	14
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	1 (7%)	3 (21%)
Non-responder	4 (27%)	3 (21%)
Missing [1]	10 (67%)	8 (57%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.26
95% C.I.		(0.02, 2.88)
p-value		0.274
Inverse Relative Risk [3]		0.31
95% C.I.		(0.04, 2.65)
p-value		0.286
Risk Difference (%) [4]		-14.76
95% C.I.		(-39.69, 10.16)
p-value		0.330

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Table 24.82
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Region - QualityMetric Approach

Region: North America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	502	503
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	99 (20%)	111 (22%)
Non-responder	107 (21%)	89 (18%)
Missing [1]	296 (59%)	303 (60%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		0.87
95% C.I.		(0.64, 1.18)
p-value		0.361
Inverse Relative Risk [3]		0.89
95% C.I.		(0.70, 1.14)
p-value		0.361
Risk Difference (%) [4]		-2.35
95% C.I.		(-7.37, 2.68)
p-value		0.394

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

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Table 24.82
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Region - QualityMetric Approach

Region: South America
Visit: Day 29

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	12	11
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	4 (33%)	1 (9%)
Non-responder	0	2 (18%)
Missing [1]	8 (67%)	8 (73%)
VIR-7831 500 mg vs. Placebo:		
Inverse Odds Ratio [2]		5.00
95% C.I.		(0.46, 54.04)
p-value		0.186
Inverse Relative Risk [3]		3.67
95% C.I.		(0.48, 28.00)
p-value		0.211
Risk Difference (%) [4]		24.24
95% C.I.		(-7.38, 55.87)
p-value		0.317

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, region (North America, Europe, South America) and region by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of VIR over Placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.20
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Age Group (<=70, >70)

Age group (years): <=70

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		473	472
Baseline	Work time missed due to health (%)	n	168	200
		Mean	51.81	56.33
		SD	39.125	39.615
		Median	53.29	56.35
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	86	107
		Mean	13.33	11.68
		SD	28.475	27.383
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in work time missed due to health (%)	n	56	74
		Mean	-31.74	-38.38
		SD	45.907	48.500
		Median	-18.75	-30.80
		Min.	-100.0	-100.0
		Max.	100.0	71.4

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.20
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Age Group (<=70, >70)

Age group (years): <=70

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	62	62
		Mean	49.03	40.81
		SD	31.032	29.659
		Median	50.00	40.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Impairment while working due to health (%)	n	61	70
		Mean	22.95	24.14
		SD	17.921	23.125
		Median	20.00	10.00
		Min.	0.0	0.0
		Max.	80.0	100.0
	Change from baseline in impairment while working due to health (%)	n	17	22
		Mean	-23.53	-15.45
		SD	37.573	28.905
		Median	-20.00	0.00
		Min.	-80.0	-90.0
		Max.	50.0	20.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.20
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Age Group (<=70, >70)

Age group (years): <=70

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	62	62
		Mean	64.23	53.86
		SD	29.983	32.651
		Median	68.88	66.62
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Overall work impairment due to health (%)	n	61	70
		Mean	28.00	28.27
		SD	22.829	25.734
		Median	20.00	20.00
		Min.	0.0	0.0
		Max.	92.5	100.0
	Change from baseline in overall work impairment due to health (%)	n	17	22
		Mean	-33.31	-19.33
		SD	41.902	32.904
		Median	-33.10	-18.18
		Min.	-86.9	-90.0
		Max.	59.1	44.6

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.20
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Age Group (<=70, >70)

Age group (years): <=70

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	182	168
		Mean	60.82	55.36
		SD	29.581	31.997
		Median	70.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	161	161
		Mean	28.26	25.09
		SD	25.680	25.596
		Median	20.00	10.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in activity impairment due to health (%)	n	93	88
		Mean	-32.80	-31.93
		SD	35.182	36.886
		Median	-40.00	-30.00
		Min.	-100.0	-90.0
		Max.	60.0	70.0

Note: WPAI was scheduled for the Expansion phase only.

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Population: Intent-to-Treat Data as of 27APR2021

Table 24.20
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Age Group (<=70, >70)

Age group (years): >70

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		56	56
Baseline	Work time missed due to health (%)	n	3	4
		Mean	52.88	75.00
		SD	41.614	50.000
		Median	37.50	100.00
		Min.	21.2	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	1	0
		Mean	0.00	
		SD		
		Median	0.00	
		Min.	0.0	
		Max.	0.0	
	Change from baseline in work time missed due to health (%)	n	0	0
		Mean		
		SD		
		Median		
		Min.		
		Max.		

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.20
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Age Group (<=70, >70)

Age group (years): >70

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	0	1
		Mean		60.00
		SD		
		Median		60.00
		Min.		60.0
		Max.		60.0
Day 29	Impairment while working due to health (%)	n	1	1
		Mean	70.00	40.00
		SD		
		Median	70.00	40.00
		Min.	70.0	40.0
		Max.	70.0	40.0
	Change from baseline in impairment while working due to health (%)	n	0	1
		Mean		-20.00
		SD		
		Median		-20.00
		Min.		-20.0
		Max.		-20.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.20
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Age Group (<=70, >70)

Age group (years): >70

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	0	0
		Mean		
		SD		
		Median		
		Min.		
		Max.		
Day 29	Overall work impairment due to health (%)	n	1	0
		Mean	70.00	
		SD		
		Median	70.00	
		Min.	70.0	
		Max.	70.0	
	Change from baseline in overall work impairment due to health (%)	n	0	0
		Mean		
		SD		
		Median		
		Min.		
		Max.		

Note: WPAI was scheduled for the Expansion phase only.

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Table 24.20
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Age Group (<=70, >70)

Age group (years): >70

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	19	21
		Mean	63.68	50.95
		SD	22.903	28.090
		Median	70.00	50.00
		Min.	10.0	0.0
		Max.	90.0	90.0
Day 29	Activity impairment due to health (%)	n	17	16
		Mean	25.88	20.00
		SD	25.995	14.606
		Median	10.00	10.00
		Min.	0.0	10.0
		Max.	90.0	60.0
	Change from baseline in activity impairment due to health (%)	n	7	7
		Mean	-34.29	-7.14
		SD	29.921	40.297
		Median	-50.00	0.00
		Min.	-70.0	-80.0
		Max.	0.0	50.0

Note: WPAI was scheduled for the Expansion phase only.

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Table 24.21
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Work time missed due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	473	472
n	56	74
LS Mean (SE)	13.63 (3.933)	13.24 (3.419)
95% C.I.	(5.85, 21.41)	(6.47, 20.01)
LS Mean Change from Baseline (SE)	-35.30 (3.933)	-35.68 (3.419)
95% C.I.	(-43.08, -27.51)	(-42.45, -28.92)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.39 (5.220)
95% C.I.		(-10.72, 9.94)
p-value		0.941
Corrected Hedge’s g (SE) [1]		-0.01 (0.177)
95% C.I.		(-0.36, 0.33)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.21
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Impairment while working due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	17	22
LS Mean (SE)	25.03 (4.673)	24.41 (4.110)
95% C.I.	(15.56, 34.51)	(16.07, 32.74)
LS Mean Change from Baseline (SE)	-18.97 (4.673)	-19.59 (4.110)
95% C.I.	(-28.44, -9.49)	(-27.93, -11.26)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.63 (6.264)
95% C.I.		(-13.33, 12.08)
p-value		0.920
Corrected Hedge’s g (SE) [1]		-0.03 (0.323)
95% C.I.		(-0.66, 0.60)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: WPAI was scheduled for the Expansion phase only.

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Table 24.21
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI)
Scores at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	17	22
LS Mean (SE)	28.08 (5.605)	31.08 (4.916)
95% C.I.	(16.71, 39.45)	(21.11, 41.05)
LS Mean Change from Baseline (SE)	-27.12 (5.605)	-24.12 (4.916)
95% C.I.	(-38.48, -15.75)	(-34.09, -14.15)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.00 (7.520)
95% C.I.		(-12.25, 18.25)
p-value		0.693
Corrected Hedge’s g (SE) [1]		0.13 (0.323)
95% C.I.		(-0.51, 0.76)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.21
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Age Group (<=70, >70)

Age group (years): <=70
Domain: Activity impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	93	88
LS Mean (SE)	28.41 (2.614)	26.77 (2.685)
95% C.I.	(23.26, 33.57)	(21.47, 32.06)
LS Mean Change from Baseline (SE)	-31.23 (2.614)	-32.87 (2.685)
95% C.I.	(-36.38, -26.07)	(-38.17, -27.58)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-1.65 (3.749)
95% C.I.		(-9.04, 5.75)
p-value		0.661
Corrected Hedge’s g (SE) [1]		-0.07 (0.149)
95% C.I.		(-0.36, 0.23)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.21
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI)
Scores at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Work time missed due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	56	56
n	0	0

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.21
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI)
Scores at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Impairment while working due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	0	1

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.21
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI)
Scores at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	0	0

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.21
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI)
Scores at Day 29 by Age Group (<=70, >70)

Age group (years): >70
Domain: Activity impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	7	7
LS Mean (SE)	37.68 (9.558)	31.15 (9.637)
95% C.I.	(18.83, 56.54)	(12.15, 50.16)
LS Mean Change from Baseline (SE)	-21.96 (9.558)	-28.49 (9.637)
95% C.I.	(-40.81, -3.10)	(-47.50, -9.48)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-6.53 (13.669)
95% C.I.		(-33.49, 20.43)
p-value		0.633
Corrected Hedge’s g (SE) [1]		-0.24 (0.536)
95% C.I.		(-1.29, 0.81)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, age (<=70, >70 years old), baseline and treatment by age interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		96	98
Baseline	Work time missed due to health (%)	n	24	31
		Mean	75.41	70.89
		SD	32.343	40.813
		Median	93.24	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	11	18
		Mean	20.21	9.51
		SD	31.374	25.648
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in work time missed due to health (%)	n	5	13
		Mean	-40.07	-55.83
		SD	59.067	44.874
		Median	-36.49	-52.63
		Min.	-100.0	-100.0
		Max.	18.2	0.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	9	10
		Mean	54.44	33.00
		SD	36.780	24.967
		Median	70.00	20.00
		Min.	0.0	10.0
		Max.	90.0	80.0
Day 29	Impairment while working due to health (%)	n	8	13
		Mean	25.00	21.54
		SD	16.036	26.409
		Median	25.00	10.00
		Min.	0.0	0.0
		Max.	50.0	100.0
	Change from baseline in impairment while working due to health (%)	n	2	5
		Mean	0.00	-16.00
		SD	70.711	15.166
		Median	0.00	-10.00
		Min.	-50.0	-40.0
		Max.	50.0	0.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	9	10
		Mean	75.08	43.04
		SD	32.408	31.392
		Median	95.61	40.33
		Min.	0.0	10.0
		Max.	98.6	90.0
Day 29	Overall work impairment due to health (%)	n	8	13
		Mean	33.39	23.00
		SD	21.107	26.841
		Median	34.00	10.00
		Min.	0.0	0.0
		Max.	60.0	100.0
	Change from baseline in overall work impairment due to health (%)	n	2	5
		Mean	11.57	-24.02
		SD	67.201	19.515
		Median	11.57	-24.00
		Min.	-35.9	-46.7
		Max.	59.1	0.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	47	47
		Mean	60.00	53.19
		SD	28.742	34.459
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	27	34
		Mean	22.96	22.35
		SD	23.007	26.521
		Median	10.00	10.00
		Min.	0.0	0.0
		Max.	90.0	100.0
	Change from baseline in activity impairment due to health (%)	n	18	23
		Mean	-37.22	-28.70
		SD	41.981	38.294
		Median	-50.00	-20.00
		Min.	-80.0	-80.0
		Max.	60.0	70.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		84	72
Baseline	Work time missed due to health (%)	n	22	25
		Mean	58.64	68.17
		SD	41.270	33.849
		Median	72.22	70.59
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	6	11
		Mean	55.06	5.07
		SD	47.547	11.353
		Median	65.18	0.00
		Min.	0.0	0.0
		Max.	100.0	30.8
	Change from baseline in work time missed due to health (%)	n	5	5
		Mean	-22.93	-86.35
		SD	77.136	24.784
		Median	0.00	-100.00
		Min.	-100.0	-100.0
		Max.	80.0	-42.9

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	8	4
		Mean	45.00	57.50
		SD	33.381	17.078
		Median	50.00	55.00
		Min.	10.0	40.0
		Max.	90.0	80.0
Day 29	Impairment while working due to health (%)	n	4	7
		Mean	25.00	14.29
		SD	17.321	11.339
		Median	25.00	10.00
		Min.	10.0	10.0
		Max.	40.0	40.0
	Change from baseline in impairment while working due to health (%)	n	0	0
		Mean		
		SD		
		Median		
		Min.		
		Max.		

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	8	4
		Mean	51.76	77.94
		SD	37.098	9.276
		Median	57.94	75.32
		Min.	10.0	70.0
		Max.	94.9	91.1
Day 29	Overall work impairment due to health (%)	n	4	7
		Mean	44.55	18.24
		SD	41.370	14.091
		Median	37.86	10.00
		Min.	10.0	10.0
		Max.	92.5	40.0
	Change from baseline in overall work impairment due to health (%)	n	0	0
		Mean		
		SD		
		Median		
		Min.		
		Max.		

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	32	22
		Mean	58.44	55.91
		SD	30.279	29.058
		Median	70.00	50.00
		Min.	0.0	10.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	30	21
		Mean	29.33	19.05
		SD	27.029	19.469
		Median	15.00	10.00
		Min.	0.0	10.0
		Max.	90.0	80.0
	Change from baseline in activity impairment due to health (%)	n	19	7
		Mean	-26.84	-47.14
		SD	41.238	34.503
		Median	-20.00	-30.00
		Min.	-90.0	-90.0
		Max.	50.0	-10.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		58	64
Baseline	Work time missed due to health (%)	n	17	28
		Mean	49.61	68.48
		SD	37.765	38.424
		Median	46.15	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	11	13
		Mean	2.60	4.05
		SD	8.615	8.518
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	28.6	25.0
	Change from baseline in work time missed due to health (%)	n	5	10
		Mean	-25.67	-55.27
		SD	17.409	37.040
		Median	-20.00	-50.85
		Min.	-46.2	-100.0
		Max.	-9.1	0.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	6	5
		Mean	43.33	42.00
		SD	21.602	25.884
		Median	45.00	50.00
		Min.	10.0	10.0
		Max.	70.0	70.0
Day 29	Impairment while working due to health (%)	n	5	9
		Mean	32.00	37.78
		SD	13.038	34.561
		Median	30.00	30.00
		Min.	20.0	0.0
		Max.	50.0	100.0
	Change from baseline in impairment while working due to health (%)	n	1	2
		Mean	10.00	-30.00
		SD		14.142
		Median	10.00	-30.00
		Min.	10.0	-40.0
		Max.	10.0	-20.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	6	4
		Mean	62.15	55.28
		SD	23.123	33.073
		Median	63.79	63.50
		Min.	24.4	10.0
		Max.	86.7	84.1
Day 29	Overall work impairment due to health (%)	n	5	8
		Mean	32.00	39.25
		SD	13.038	36.862
		Median	30.00	25.00
		Min.	20.0	0.0
		Max.	50.0	100.0
	Change from baseline in overall work impairment due to health (%)	n	1	1
		Mean	-15.26	-40.12
		SD		
		Median	-15.26	-40.12
		Min.	-15.3	-40.1
		Max.	-15.3	-40.1

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	21	22
		Mean	66.19	58.64
		SD	27.835	32.263
		Median	70.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	21	16
		Mean	31.90	27.50
		SD	24.004	27.203
		Median	20.00	15.00
		Min.	10.0	0.0
		Max.	90.0	90.0
	Change from baseline in activity impairment due to health (%)	n	11	8
		Mean	-32.73	-35.00
		SD	26.112	40.356
		Median	-40.00	-45.00
		Min.	-70.0	-80.0
		Max.	10.0	10.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		60	74
Baseline	Work time missed due to health (%)	n	22	29
		Mean	48.69	44.52
		SD	38.746	40.747
		Median	45.52	38.46
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	11	17
		Mean	3.94	6.47
		SD	9.161	15.742
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	30.4	54.5
	Change from baseline in work time missed due to health (%)	n	7	10
		Mean	-39.24	-38.97
		SD	44.492	55.791
		Median	-15.25	-37.35
		Min.	-100.0	-100.0
		Max.	0.0	49.5

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	8	13
		Mean	56.25	46.15
		SD	31.595	31.235
		Median	65.00	50.00
		Min.	20.0	10.0
		Max.	90.0	100.0
Day 29	Impairment while working due to health (%)	n	9	14
		Mean	24.44	22.86
		SD	22.973	21.989
		Median	20.00	10.00
		Min.	10.0	10.0
		Max.	80.0	70.0
	Change from baseline in impairment while working due to health (%)	n	2	5
		Mean	-30.00	-24.00
		SD	42.426	39.115
		Median	-30.00	0.00
		Min.	-60.0	-90.0
		Max.	0.0	0.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	8	13
		Mean	63.16	52.47
		SD	32.660	32.675
		Median	71.67	70.00
		Min.	20.0	10.0
		Max.	96.5	100.0
Day 29	Overall work impairment due to health (%)	n	9	14
		Mean	25.53	28.34
		SD	22.891	24.846
		Median	20.00	10.00
		Min.	10.0	10.0
		Max.	80.0	81.1
	Change from baseline in overall work impairment due to health (%)	n	2	5
		Mean	-30.19	-14.72
		SD	42.700	50.474
		Median	-30.19	0.00
		Min.	-60.4	-90.0
		Max.	0.0	44.6

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	22	30
		Mean	64.09	61.00
		SD	25.941	29.048
		Median	70.00	70.00
		Min.	10.0	10.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	23	34
		Mean	21.74	23.24
		SD	21.031	25.669
		Median	10.00	10.00
		Min.	0.0	0.0
		Max.	80.0	90.0
	Change from baseline in activity impairment due to health (%)	n	13	18
		Mean	-43.85	-36.11
		SD	27.850	31.834
		Median	-40.00	-35.00
		Min.	-90.0	-80.0
		Max.	0.0	0.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		183	159
Baseline	Work time missed due to health (%)	n	73	66
		Mean	43.85	47.09
		SD	38.286	38.268
		Median	40.00	46.41
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	37	37
		Mean	12.86	19.19
		SD	29.507	36.442
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in work time missed due to health (%)	n	29	29
		Mean	-30.73	-16.28
		SD	44.000	40.935
		Median	-26.19	0.00
		Min.	-100.0	-100.0
		Max.	100.0	64.3

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	24	20
		Mean	50.00	33.50
		SD	32.303	29.429
		Median	50.00	25.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Impairment while working due to health (%)	n	26	20
		Mean	23.46	26.00
		SD	19.988	20.365
		Median	10.00	20.00
		Min.	0.0	0.0
		Max.	70.0	70.0
	Change from baseline in impairment while working due to health (%)	n	9	9
		Mean	-30.00	-3.33
		SD	37.417	20.616
		Median	-20.00	0.00
		Min.	-80.0	-50.0
		Max.	20.0	20.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	24	20
		Mean	63.55	53.33
		SD	30.380	33.883
		Median	68.33	62.71
		Min.	10.0	0.0
		Max.	100.0	100.0
Day 29	Overall work impairment due to health (%)	n	26	20
		Mean	28.30	31.08
		SD	23.366	27.511
		Median	20.00	22.79
		Min.	0.0	0.0
		Max.	73.0	87.5
	Change from baseline in overall work impairment due to health (%)	n	9	9
		Mean	-37.21	-13.50
		SD	39.835	26.285
		Median	-33.10	-17.69
		Min.	-86.7	-56.4
		Max.	20.0	21.4

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.31
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	62	48
		Mean	61.13	46.04
		SD	29.203	29.732
		Median	70.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	61	51
		Mean	31.97	28.63
		SD	28.799	25.847
		Median	20.00	20.00
		Min.	0.0	0.0
		Max.	100.0	90.0
	Change from baseline in activity impairment due to health (%)	n	29	28
		Mean	-27.93	-13.57
		SD	30.866	31.295
		Median	-20.00	-5.00
		Min.	-90.0	-70.0
		Max.	20.0	50.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Work time missed due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	96	98
n	5	13
LS Mean (SE)	30.64 (12.835)	10.74 (8.007)
95% C.I.	(5.19, 56.08)	(-5.13, 26.62)
LS Mean Change from Baseline (SE)	-18.56 (12.835)	-38.45 (8.007)
95% C.I.	(-44.00, 6.89)	(-54.32, -22.58)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-19.89 (14.976)
95% C.I.		(-49.58, 9.79)
p-value		0.187
Corrected Hedge’s g (SE) [1]		-0.66 (0.538)
95% C.I.		(-1.71, 0.40)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Impairment while working due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	2	5
LS Mean (SE)	36.51 (14.087)	13.08 (9.139)
95% C.I.	(7.56, 65.47)	(-5.71, 31.87)
LS Mean Change from Baseline (SE)	-7.20 (14.087)	-30.63 (9.139)
95% C.I.	(-36.15, 21.76)	(-49.42, -11.85)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-23.44 (16.656)
95% C.I.		(-57.67, 10.80)
p-value		0.171
Corrected Hedge’s g (SE) [1]		-0.97 (0.876)
95% C.I.		(-2.69, 0.75)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	2	5
LS Mean (SE)	60.69 (15.997)	17.01 (10.278)
95% C.I.	(27.75, 93.64)	(-4.16, 38.18)
LS Mean Change from Baseline (SE)	7.05 (15.997)	-36.63 (10.278)
95% C.I.	(-25.89, 40.00)	(-57.80, -15.46)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-43.68 (18.949)
95% C.I.		(-82.71, -4.65)
p-value		0.030
Corrected Hedge’s g (SE) [1]		-1.61 (0.940)
95% C.I.		(-3.45, 0.24)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Activity impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	18	23
LS Mean (SE)	23.36 (5.968)	22.86 (5.311)
95% C.I.	(11.57, 35.14)	(12.37, 33.34)
LS Mean Change from Baseline (SE)	-35.32 (5.968)	-35.82 (5.311)
95% C.I.	(-47.10, -23.54)	(-46.31, -25.34)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.50 (8.000)
95% C.I.		(-16.30, 15.30)
p-value		0.950
Corrected Hedge’s g (SE) [1]		-0.02 (0.315)
95% C.I.		(-0.64, 0.60)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Work time missed due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	84	72
n	5	5
LS Mean (SE)	45.84 (12.816)	-4.55 (12.977)
95% C.I.	(20.44, 71.25)	(-30.27, 21.18)
LS Mean Change from Baseline (SE)	-3.35 (12.816)	-53.74 (12.977)
95% C.I.	(-28.76, 22.05)	(-79.47, -28.02)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-50.39 (18.023)
95% C.I.		(-86.12, -14.66)
p-value		0.006
Corrected Hedge’s g (SE) [1]		-1.58 (0.724)
95% C.I.		(-3.00, -0.16)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Impairment while working due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	0	0

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	0	0

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Activity impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	19	7
LS Mean (SE)	32.87 (5.807)	22.62 (9.611)
95% C.I.	(21.40, 44.34)	(3.65, 41.60)
LS Mean Change from Baseline (SE)	-25.81 (5.807)	-36.06 (9.611)
95% C.I.	(-37.28, -14.34)	(-55.03, -17.08)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-10.25 (11.222)
95% C.I.		(-32.41, 11.91)
p-value		0.363
Corrected Hedge’s g (SE) [1]		-0.39 (0.445)
95% C.I.		(-1.26, 0.48)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Work time missed due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	58	64
n	5	10
LS Mean (SE)	7.89 (12.782)	3.88 (9.031)
95% C.I.	(-17.45, 33.23)	(-14.02, 21.78)
LS Mean Change from Baseline (SE)	-41.30 (12.782)	-45.31 (9.031)
95% C.I.	(-66.64, -15.96)	(-63.22, -27.41)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-4.01 (15.711)
95% C.I.		(-35.16, 27.13)
p-value		0.799
Corrected Hedge’s g (SE) [1]		-0.13 (0.548)
95% C.I.		(-1.21, 0.94)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Impairment while working due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	1	2
LS Mean (SE)	50.65 (19.871)	31.30 (14.281)
95% C.I.	(9.80, 91.49)	(1.94, 60.66)
LS Mean Change from Baseline (SE)	6.93 (19.871)	-12.41 (14.281)
95% C.I.	(-33.91, 47.78)	(-41.77, 16.94)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-19.35 (24.518)
95% C.I.		(-69.74, 31.05)
p-value		0.437
Corrected Hedge’s g (SE) [1]		0.00 (1.225)
95% C.I.		(-2.40, 2.40)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	1	1

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Activity impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	11	8
LS Mean (SE)	36.94 (7.686)	28.62 (8.958)
95% C.I.	(21.76, 52.11)	(10.93, 46.31)
LS Mean Change from Baseline (SE)	-21.74 (7.686)	-30.06 (8.958)
95% C.I.	(-36.92, -6.56)	(-47.75, -12.37)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-8.32 (11.772)
95% C.I.		(-31.56, 14.93)
p-value		0.481
Corrected Hedge’s g (SE) [1]		-0.31 (0.467)
95% C.I.		(-1.23, 0.60)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Work time missed due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	60	74
n	7	10
LS Mean (SE)	2.09 (10.771)	9.27 (8.997)
95% C.I.	(-19.26, 23.45)	(-8.56, 27.11)
LS Mean Change from Baseline (SE)	-47.10 (10.771)	-39.92 (8.997)
95% C.I.	(-68.45, -25.75)	(-57.76, -22.09)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		7.18 (14.031)
95% C.I.		(-20.64, 34.99)
p-value		0.610
Corrected Hedge’s g (SE) [1]		0.24 (0.495)
95% C.I.		(-0.73, 1.21)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Impairment while working due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	2	5
LS Mean (SE)	14.78 (14.048)	26.56 (8.941)
95% C.I.	(-14.10, 43.65)	(8.18, 44.94)
LS Mean Change from Baseline (SE)	-28.94 (14.048)	-17.15 (8.941)
95% C.I.	(-57.81, -0.06)	(-35.53, 1.22)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		11.78 (16.642)
95% C.I.		(-22.43, 45.99)
p-value		0.485
Corrected Hedge’s g (SE) [1]		0.50 (0.847)
95% C.I.		(-1.16, 2.16)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	2	5
LS Mean (SE)	19.21 (15.996)	39.80 (10.110)
95% C.I.	(-13.73, 52.16)	(18.98, 60.63)
LS Mean Change from Baseline (SE)	-34.42 (15.996)	-13.83 (10.110)
95% C.I.	(-67.37, -1.48)	(-34.66, 6.99)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		20.59 (18.927)
95% C.I.		(-18.39, 59.57)
p-value		0.287
Corrected Hedge’s g (SE) [1]		0.77 (0.861)
95% C.I.		(-0.92, 2.46)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Activity impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	13	18
LS Mean (SE)	22.48 (7.049)	26.21 (5.974)
95% C.I.	(8.56, 36.40)	(14.41, 38.00)
LS Mean Change from Baseline (SE)	-36.20 (7.049)	-32.47 (5.974)
95% C.I.	(-50.11, -22.28)	(-44.27, -20.68)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.72 (9.219)
95% C.I.		(-14.48, 21.93)
p-value		0.687
Corrected Hedge’s g (SE) [1]		0.14 (0.364)
95% C.I.		(-0.57, 0.86)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Work time missed due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	183	159
n	29	29
LS Mean (SE)	10.60 (5.319)	21.77 (5.355)
95% C.I.	(0.06, 21.15)	(11.15, 32.38)
LS Mean Change from Baseline (SE)	-38.59 (5.319)	-27.43 (5.355)
95% C.I.	(-49.14, -28.05)	(-38.04, -16.81)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		11.16 (7.476)
95% C.I.		(-3.66, 25.98)
p-value		0.138
Corrected Hedge’s g (SE) [1]		0.38 (0.265)
95% C.I.		(-0.14, 0.90)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

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Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Impairment while working due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	9	9
LS Mean (SE)	26.25 (6.872)	29.97 (6.795)
95% C.I.	(12.13, 40.38)	(16.00, 43.94)
LS Mean Change from Baseline (SE)	-17.46 (6.872)	-13.75 (6.795)
95% C.I.	(-31.59, -3.34)	(-27.71, 0.22)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.72 (9.950)
95% C.I.		(-16.74, 24.17)
p-value		0.712
Corrected Hedge’s g (SE) [1]		0.17 (0.472)
95% C.I.		(-0.75, 1.10)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

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Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	9	9
LS Mean (SE)	26.63 (7.683)	34.66 (7.578)
95% C.I.	(10.81, 42.46)	(19.05, 50.27)
LS Mean Change from Baseline (SE)	-27.01 (7.683)	-18.98 (7.578)
95% C.I.	(-42.83, -11.18)	(-34.58, -3.37)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		8.03 (10.903)
95% C.I.		(-14.43, 30.48)
p-value		0.468
Corrected Hedge’s g (SE) [1]		0.33 (0.475)
95% C.I.		(-0.60, 1.26)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.32
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Activity impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	29	28
LS Mean (SE)	30.97 (4.700)	34.41 (4.865)
95% C.I.	(21.69, 40.25)	(24.80, 44.02)
LS Mean Change from Baseline (SE)	-27.71 (4.700)	-24.27 (4.865)
95% C.I.	(-36.99, -18.43)	(-33.87, -14.66)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		3.44 (6.767)
95% C.I.		(-9.92, 16.80)
p-value		0.612
Corrected Hedge’s g (SE) [1]		0.13 (0.265)
95% C.I.		(-0.39, 0.65)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, baseline viral load category, baseline and treatment by baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.

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Table 24.42
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Gender

Gender: Male

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		256	229
Baseline	Work time missed due to health (%)	n	87	89
		Mean	54.89	61.26
		SD	41.044	38.597
		Median	55.56	60.76
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	48	51
		Mean	12.00	12.67
		SD	27.056	29.358
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in work time missed due to health (%)	n	30	30
		Mean	-30.50	-32.19
		SD	41.383	51.539
		Median	-18.75	-28.20
		Min.	-100.0	-100.0
		Max.	80.0	71.4

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.42
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Gender

Gender: Male

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	28	24
		Mean	44.64	43.75
		SD	28.607	29.754
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	90.0	100.0
Day 29	Impairment while working due to health (%)	n	36	33
		Mean	20.83	22.12
		SD	15.561	23.151
		Median	10.00	10.00
		Min.	10.0	0.0
		Max.	70.0	100.0
	Change from baseline in impairment while working due to health (%)	n	11	10
		Mean	-21.82	-23.00
		SD	27.863	27.101
		Median	-20.00	-20.00
		Min.	-60.0	-80.0
		Max.	20.0	10.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.42
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Gender

Gender: Male

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	28	23
		Mean	60.27	59.21
		SD	28.157	29.868
		Median	63.03	64.00
		Min.	10.0	0.0
		Max.	98.6	100.0
Day 29	Overall work impairment due to health (%)	n	36	32
		Mean	25.56	25.96
		SD	19.261	27.033
		Median	20.00	10.00
		Min.	10.0	0.0
		Max.	72.7	100.0
	Change from baseline in overall work impairment due to health (%)	n	11	9
		Mean	-28.89	-31.05
		SD	30.792	30.283
		Median	-20.00	-36.00
		Min.	-86.9	-80.0
		Max.	20.0	21.4

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.42
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Gender

Gender: Male

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	97	76
		Mean	60.41	56.05
		SD	28.465	30.641
		Median	70.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	78	75
		Mean	26.03	20.80
		SD	24.513	21.795
		Median	10.00	10.00
		Min.	0.0	0.0
		Max.	100.0	90.0
	Change from baseline in activity impairment due to health (%)	n	43	41
		Mean	-35.58	-36.59
		SD	34.524	33.362
		Median	-40.00	-30.00
		Min.	-100.0	-80.0
		Max.	50.0	10.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.42
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Gender

Gender: Female

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		273	299
Baseline	Work time missed due to health (%)	n	84	115
		Mean	48.67	53.17
		SD	36.828	40.478
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	39	56
		Mean	14.62	10.77
		SD	30.151	25.688
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in work time missed due to health (%)	n	26	44
		Mean	-33.16	-42.60
		SD	51.438	46.442
		Median	-23.59	-36.13
		Min.	-100.0	-100.0
		Max.	100.0	49.5

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.42
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Gender

Gender: Female

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	34	39
		Mean	52.65	39.49
		SD	32.873	29.642
		Median	60.00	40.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Impairment while working due to health (%)	n	26	38
		Mean	27.69	26.32
		SD	22.146	23.065
		Median	20.00	20.00
		Min.	0.0	0.0
		Max.	80.0	100.0
	Change from baseline in impairment while working due to health (%)	n	6	13
		Mean	-26.67	-10.00
		SD	54.283	28.868
		Median	-30.00	0.00
		Min.	-80.0	-90.0
		Max.	50.0	20.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.42
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Gender

Gender: Female

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	34	39
		Mean	67.50	50.70
		SD	31.445	34.167
		Median	77.67	69.23
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Overall work impairment due to health (%)	n	26	38
		Mean	32.99	30.22
		SD	27.706	24.783
		Median	20.00	20.00
		Min.	0.0	0.0
		Max.	92.5	100.0
	Change from baseline in overall work impairment due to health (%)	n	6	13
		Mean	-41.42	-11.22
		SD	60.002	33.301
		Median	-73.65	0.00
		Min.	-86.7	-90.0
		Max.	59.1	44.6

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.42
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Gender

Gender: Female

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	104	113
		Mean	61.73	54.07
		SD	29.574	32.256
		Median	70.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	100	102
		Mean	29.60	27.45
		SD	26.512	26.576
		Median	20.00	10.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in activity impairment due to health (%)	n	57	54
		Mean	-30.88	-25.19
		SD	35.014	39.941
		Median	-40.00	-20.00
		Min.	-90.0	-90.0
		Max.	60.0	70.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.43
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Gender

Gender: Male
Domain: Work time missed due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	256	229
n	30	30
LS Mean (SE)	14.38 (5.398)	16.58 (5.390)
95% C.I.	(3.70, 25.06)	(5.91, 27.25)
LS Mean Change from Baseline (SE)	-34.54 (5.398)	-32.35 (5.390)
95% C.I.	(-45.23, -23.86)	(-43.01, -21.68)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.20 (7.628)
95% C.I.		(-12.90, 17.30)
p-value		0.774
Corrected Hedge’s g (SE) [1]		0.07 (0.258)
95% C.I.		(-0.43, 0.58)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.43
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Gender

Gender: Male
Domain: Impairment while working due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	11	10
LS Mean (SE)	23.40 (5.811)	21.00 (6.092)
95% C.I.	(11.60, 35.19)	(8.63, 33.37)
LS Mean Change from Baseline (SE)	-20.60 (5.811)	-23.00 (6.092)
95% C.I.	(-32.40, -8.81)	(-35.37, -10.63)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.40 (8.419)
95% C.I.		(-19.49, 14.70)
p-value		0.778
Corrected Hedge’s g (SE) [1]		-0.12 (0.437)
95% C.I.		(-0.98, 0.74)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: WPAI was scheduled for the Expansion phase only.

Table 24.43
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Gender

Gender: Male
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	11	9
LS Mean (SE)	27.57 (6.998)	25.19 (7.735)
95% C.I.	(13.35, 41.79)	(9.47, 40.91)
LS Mean Change from Baseline (SE)	-27.63 (6.998)	-30.00 (7.735)
95% C.I.	(-41.85, -13.40)	(-45.72, -14.28)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.38 (10.429)
95% C.I.		(-23.57, 18.82)
p-value		0.821
Corrected Hedge’s g (SE) [1]		-0.10 (0.450)
95% C.I.		(-0.98, 0.78)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.43
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Gender

Gender: Male
Domain: Activity impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	43	41
LS Mean (SE)	24.36 (3.810)	23.56 (3.902)
95% C.I.	(16.85, 31.88)	(15.87, 31.26)
LS Mean Change from Baseline (SE)	-35.28 (3.810)	-36.08 (3.902)
95% C.I.	(-42.80, -27.76)	(-43.78, -28.38)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.80 (5.454)
95% C.I.		(-11.56, 9.96)
p-value		0.884
Corrected Hedge’s g (SE) [1]		-0.03 (0.218)
95% C.I.		(-0.46, 0.40)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.43
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Gender

Gender: Female
Domain: Work time missed due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	273	299
n	26	44
LS Mean (SE)	12.78 (5.794)	10.95 (4.463)
95% C.I.	(1.32, 24.25)	(2.12, 19.78)
LS Mean Change from Baseline (SE)	-36.14 (5.794)	-37.97 (4.463)
95% C.I.	(-47.61, -24.67)	(-46.81, -29.14)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-1.83 (7.323)
95% C.I.		(-16.32, 12.66)
p-value		0.803
Corrected Hedge’s g (SE) [1]		-0.06 (0.247)
95% C.I.		(-0.55, 0.42)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: WPAI was scheduled for the Expansion phase only.

Table 24.43
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Gender

Gender: Female
Domain: Impairment while working due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	6	13
LS Mean (SE)	27.90 (7.965)	28.10 (5.389)
95% C.I.	(11.73, 44.07)	(17.15, 39.04)
LS Mean Change from Baseline (SE)	-16.10 (7.965)	-15.90 (5.389)
95% C.I.	(-32.27, 0.07)	(-26.85, -4.96)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.20 (9.709)
95% C.I.		(-19.52, 19.91)
p-value		0.984
Corrected Hedge’s g (SE) [1]		0.01 (0.494)
95% C.I.		(-0.96, 0.98)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.43
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Gender

Gender: Female
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	6	13
LS Mean (SE)	28.76 (9.684)	35.27 (6.541)
95% C.I.	(9.08, 48.44)	(21.97, 48.56)
LS Mean Change from Baseline (SE)	-26.44 (9.684)	-19.93 (6.541)
95% C.I.	(-46.12, -6.76)	(-33.22, -6.64)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		6.51 (11.885)
95% C.I.		(-17.64, 30.66)
p-value		0.587
Corrected Hedge’s g (SE) [1]		0.26 (0.495)
95% C.I.		(-0.71, 1.23)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.43
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Gender

Gender: Female
Domain: Activity impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	57	54
LS Mean (SE)	32.61 (3.320)	29.77 (3.416)
95% C.I.	(26.06, 39.16)	(23.04, 36.51)
LS Mean Change from Baseline (SE)	-27.03 (3.320)	-29.87 (3.416)
95% C.I.	(-33.58, -20.48)	(-36.60, -23.13)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.83 (4.781)
95% C.I.		(-12.27, 6.60)
p-value		0.554
Corrected Hedge’s g (SE) [1]		-0.11 (0.190)
95% C.I.		(-0.48, 0.26)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, gender (male, female), baseline and treatment by gender interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

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Population: Intent-to-Treat Data as of 27APR2021

Table 24.53
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: <=1

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		307	293
Baseline	Work time missed due to health (%)	n	111	135
		Mean	51.57	54.01
		SD	39.537	39.948
		Median	51.02	54.05
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	51	64
		Mean	12.98	11.29
		SD	27.378	26.704
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in work time missed due to health (%)	n	33	44
		Mean	-33.66	-31.83
		SD	51.647	51.121
		Median	-38.10	-26.86
		Min.	-100.0	-100.0
		Max.	100.0	71.4

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.53
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: <=1

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	38	43
		Mean	50.26	40.47
		SD	35.066	30.625
		Median	50.00	30.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Impairment while working due to health (%)	n	32	42
		Mean	21.88	21.90
		SD	18.393	21.212
		Median	10.00	10.00
		Min.	0.0	0.0
		Max.	70.0	100.0
	Change from baseline in impairment while working due to health (%)	n	9	13
		Mean	-30.00	-12.31
		SD	44.721	28.330
		Median	-40.00	0.00
		Min.	-80.0	-80.0
		Max.	50.0	20.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.53
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: <=1

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	38	43
		Mean	61.73	52.00
		SD	32.957	32.760
		Median	68.88	52.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Overall work impairment due to health (%)	n	32	42
		Mean	27.66	26.01
		SD	23.869	23.425
		Median	20.00	15.00
		Min.	0.0	0.0
		Max.	92.5	100.0
	Change from baseline in overall work impairment due to health (%)	n	9	13
		Mean	-42.38	-12.88
		SD	49.216	36.045
		Median	-60.39	0.00
		Min.	-86.7	-80.0
		Max.	59.1	44.6

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.53
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: <=1

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	107	96
		Mean	62.62	54.17
		SD	28.295	32.981
		Median	70.00	60.00
		Min.	0.0	10.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	93	89
		Mean	29.46	21.80
		SD	25.765	23.382
		Median	20.00	10.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in activity impairment due to health (%)	n	51	48
		Mean	-33.33	-33.96
		SD	33.327	39.180
		Median	-40.00	-25.00
		Min.	-90.0	-90.0
		Max.	60.0	70.0

Note: WPAI was scheduled for the Expansion phase only.

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Population: Intent-to-Treat Data as of 27APR2021

Table 24.53
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: 2

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		153	178
Baseline	Work time missed due to health (%)	n	48	58
		Mean	52.90	63.23
		SD	38.727	38.968
		Median	47.56	80.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	25	37
		Mean	13.18	14.25
		SD	29.442	30.499
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in work time missed due to health (%)	n	17	27
		Mean	-29.49	-44.87
		SD	37.523	44.306
		Median	-17.50	-29.35
		Min.	-100.0	-100.0
		Max.	5.4	20.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.53
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: 2

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	17	19
		Mean	49.41	41.05
		SD	22.768	27.668
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	80.0	100.0
Day 29	Impairment while working due to health (%)	n	21	28
		Mean	26.19	25.36
		SD	21.089	21.685
		Median	20.00	15.00
		Min.	10.0	0.0
		Max.	80.0	90.0
	Change from baseline in impairment while working due to health (%)	n	6	10
		Mean	-13.33	-20.00
		SD	25.033	29.059
		Median	-20.00	-15.00
		Min.	-50.0	-90.0
		Max.	20.0	10.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.53
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: 2

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	17	18
		Mean	66.54	57.40
		SD	23.083	33.713
		Median	63.10	72.54
		Min.	10.0	0.0
		Max.	95.9	100.0
Day 29	Overall work impairment due to health (%)	n	21	27
		Mean	30.48	29.14
		SD	23.925	26.178
		Median	20.00	20.00
		Min.	10.0	0.0
		Max.	80.0	90.0
	Change from baseline in overall work impairment due to health (%)	n	6	9
		Mean	-13.78	-28.66
		SD	22.304	26.975
		Median	-20.00	-24.00
		Min.	-35.9	-90.0
		Max.	20.0	0.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.53
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: 2

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	62	73
		Mean	57.26	55.89
		SD	30.470	29.853
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	54	71
		Mean	24.26	23.38
		SD	22.453	22.229
		Median	10.00	10.00
		Min.	0.0	0.0
		Max.	90.0	90.0
	Change from baseline in activity impairment due to health (%)	n	32	39
		Mean	-32.19	-29.49
		SD	37.823	34.408
		Median	-45.00	-30.00
		Min.	-90.0	-90.0
		Max.	50.0	70.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.53
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: >=3

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		69	57
Baseline	Work time missed due to health (%)	n	12	11
		Mean	50.00	55.33
		SD	38.797	41.578
		Median	62.25	55.56
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	11	6
		Mean	14.05	0.00
		SD	32.869	0.000
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	100.0	0.0
	Change from baseline in work time missed due to health (%)	n	6	3
		Mean	-27.50	-76.09
		SD	39.265	22.413
		Median	-23.88	-72.73
		Min.	-89.7	-100.0
		Max.	17.9	-55.6

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.53
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: >=3

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	7	1
		Mean	41.43	70.00
		SD	27.343	
		Median	40.00	70.00
		Min.	10.0	70.0
		Max.	80.0	70.0
Day 29	Impairment while working due to health (%)	n	9	1
		Mean	24.44	100.00
		SD	15.092	
		Median	20.00	100.00
		Min.	10.0	100.0
		Max.	50.0	100.0
	Change from baseline in impairment while working due to health (%)	n	2	0
		Mean	-25.00	
		SD	49.497	
		Median	-25.00	
		Min.	-60.0	
		Max.	10.0	

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.53
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: >=3

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	7	1
		Mean	72.18	70.00
		SD	29.874	
		Median	82.86	70.00
		Min.	10.0	70.0
		Max.	96.9	70.0
Day 29	Overall work impairment due to health (%)	n	9	1
		Mean	28.08	100.00
		SD	21.773	
		Median	20.00	100.00
		Min.	10.0	100.0
		Max.	72.7	100.0
	Change from baseline in overall work impairment due to health (%)	n	2	0
		Mean	-51.09	
		SD	50.671	
		Median	-51.09	
		Min.	-86.9	
		Max.	-15.3	

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.53
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: >=3

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	32	20
		Mean	63.44	54.50
		SD	28.467	32.032
		Median	70.00	55.00
		Min.	0.0	10.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	31	17
		Mean	30.32	44.71
		SD	30.275	33.563
		Median	10.00	40.00
		Min.	0.0	10.0
		Max.	100.0	90.0
	Change from baseline in activity impairment due to health (%)	n	17	8
		Mean	-32.94	-10.00
		SD	34.779	39.641
		Median	-40.00	-5.00
		Min.	-100.0	-80.0
		Max.	10.0	50.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.54
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Work time missed due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	307	293
n	33	44
LS Mean (SE)	12.01 (5.160)	14.09 (4.469)
95% C.I.	(1.79, 22.22)	(5.24, 22.93)
LS Mean Change from Baseline (SE)	-36.92 (5.160)	-34.84 (4.469)
95% C.I.	(-47.13, -26.70)	(-43.68, -25.99)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.08 (6.819)
95% C.I.		(-11.42, 15.58)
p-value		0.761
Corrected Hedge’s g (SE) [1]		0.07 (0.230)
95% C.I.		(-0.38, 0.52)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.54
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Impairment while working due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	9	13
LS Mean (SE)	17.23 (6.248)	22.35 (5.298)
95% C.I.	(4.53, 29.93)	(11.58, 33.11)
LS Mean Change from Baseline (SE)	-26.77 (6.248)	-21.65 (5.298)
95% C.I.	(-39.47, -14.07)	(-32.42, -10.89)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		5.12 (8.239)
95% C.I.		(-11.63, 21.86)
p-value		0.539
Corrected Hedge’s g (SE) [1]		0.26 (0.435)
95% C.I.		(-0.59, 1.11)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.54
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	9	13
LS Mean (SE)	18.34 (7.498)	30.28 (6.406)
95% C.I.	(3.08, 33.59)	(17.25, 43.32)
LS Mean Change from Baseline (SE)	-36.86 (7.498)	-24.91 (6.406)
95% C.I.	(-52.11, -21.60)	(-37.95, -11.88)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		11.94 (9.977)
95% C.I.		(-8.35, 32.24)
p-value		0.240
Corrected Hedge’s g (SE) [1]		0.50 (0.440)
95% C.I.		(-0.36, 1.37)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.54
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: <=1
Domain: Activity impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	51	48
LS Mean (SE)	31.49 (3.462)	21.17 (3.564)
95% C.I.	(24.66, 38.32)	(14.14, 28.20)
LS Mean Change from Baseline (SE)	-28.16 (3.462)	-38.47 (3.564)
95% C.I.	(-34.99, -21.33)	(-45.50, -31.44)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-10.31 (4.990)
95% C.I.		(-20.16, -0.47)
p-value		0.040
Corrected Hedge’s g (SE) [1]		-0.41 (0.203)
95% C.I.		(-0.81, -0.02)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.54
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Work time missed due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	153	178
n	17	27
LS Mean (SE)	12.69 (7.198)	13.61 (5.739)
95% C.I.	(-1.56, 26.94)	(2.25, 24.97)
LS Mean Change from Baseline (SE)	-36.24 (7.198)	-35.32 (5.739)
95% C.I.	(-50.48, -21.99)	(-46.68, -23.96)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.92 (9.241)
95% C.I.		(-17.37, 19.21)
p-value		0.921
Corrected Hedge’s g (SE) [1]		0.03 (0.310)
95% C.I.		(-0.58, 0.64)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: WPAI was scheduled for the Expansion phase only.

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Table 24.54
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Impairment while working due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	6	10
LS Mean (SE)	35.80 (7.661)	28.28 (5.937)
95% C.I.	(20.23, 51.37)	(16.21, 40.34)
LS Mean Change from Baseline (SE)	-8.20 (7.661)	-15.72 (5.937)
95% C.I.	(-23.77, 7.37)	(-27.79, -3.66)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-7.52 (9.663)
95% C.I.		(-27.16, 12.11)
p-value		0.442
Corrected Hedge’s g (SE) [1]		-0.38 (0.521)
95% C.I.		(-1.40, 0.64)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.54
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	6	9
LS Mean (SE)	43.42 (9.144)	32.30 (7.501)
95% C.I.	(24.81, 62.02)	(17.04, 47.56)
LS Mean Change from Baseline (SE)	-11.78 (9.144)	-22.90 (7.501)
95% C.I.	(-30.38, 6.83)	(-38.16, -7.63)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-11.12 (11.811)
95% C.I.		(-35.15, 12.91)
p-value		0.353
Corrected Hedge’s g (SE) [1]		-0.47 (0.534)
95% C.I.		(-1.51, 0.58)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: WPAI was scheduled for the Expansion phase only.

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Table 24.54
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: 2
Domain: Activity impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	32	39
LS Mean (SE)	26.96 (4.349)	29.14 (3.940)
95% C.I.	(18.38, 35.54)	(21.37, 36.92)
LS Mean Change from Baseline (SE)	-32.68 (4.349)	-30.50 (3.940)
95% C.I.	(-41.26, -24.10)	(-38.27, -22.73)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		2.19 (5.868)
95% C.I.		(-9.39, 13.76)
p-value		0.710
Corrected Hedge’s g (SE) [1]		0.09 (0.239)
95% C.I.		(-0.38, 0.56)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.54
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Work time missed due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	69	57
n	6	3
LS Mean (SE)	25.32 (12.091)	-2.74 (17.184)
95% C.I.	(1.39, 49.25)	(-36.76, 31.27)
LS Mean Change from Baseline (SE)	-23.60 (12.091)	-51.67 (17.184)
95% C.I.	(-47.54, 0.33)	(-85.68, -17.65)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-28.06 (20.988)
95% C.I.		(-69.61, 13.48)
p-value		0.184
Corrected Hedge’s g (SE) [1]		-0.84 (0.734)
95% C.I.		(-2.28, 0.60)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.54
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Impairment while working due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	2	0

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.54
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	2	0

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.54
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Number of Risk Factors

Number of risk factors: >=3
Domain: Activity impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	17	8
LS Mean (SE)	26.00 (5.966)	52.09 (8.699)
95% C.I.	(14.23, 37.77)	(34.93, 69.25)
LS Mean Change from Baseline (SE)	-33.64 (5.966)	-7.55 (8.699)
95% C.I.	(-45.41, -21.87)	(-24.71, 9.61)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		26.09 (10.549)
95% C.I.		(5.28, 46.90)
p-value		0.014
Corrected Hedge’s g (SE) [1]		1.03 (0.453)
95% C.I.		(0.14, 1.91)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, number of risk factors (<=1, 2, >=3), baseline and treatment by number of risk factors interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.64
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		231	234
Baseline	Work time missed due to health (%)	n	80	101
		Mean	46.91	52.16
		SD	38.105	39.838
		Median	44.51	54.05
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	43	56
		Mean	6.18	13.46
		SD	18.567	28.981
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in work time missed due to health (%)	n	28	41
		Mean	-38.18	-31.64
		SD	34.967	49.264
		Median	-39.05	-17.50
		Min.	-100.0	-100.0
		Max.	0.0	71.4

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.64
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	34	33
		Mean	42.06	39.39
		SD	31.118	31.219
		Median	35.00	30.00
		Min.	0.0	10.0
		Max.	90.0	100.0
Day 29	Impairment while working due to health (%)	n	30	36
		Mean	22.33	21.67
		SD	17.750	23.845
		Median	20.00	10.00
		Min.	0.0	0.0
		Max.	80.0	100.0
	Change from baseline in impairment while working due to health (%)	n	11	11
		Mean	-19.09	-20.91
		SD	30.481	34.483
		Median	-20.00	0.00
		Min.	-80.0	-90.0
		Max.	20.0	10.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.64
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	34	33
		Mean	57.53	51.44
		SD	31.586	33.237
		Median	63.03	50.00
		Min.	10.0	10.0
		Max.	97.3	100.0
Day 29	Overall work impairment due to health (%)	n	30	36
		Mean	25.40	27.08
		SD	20.996	26.410
		Median	20.00	10.00
		Min.	0.0	0.0
		Max.	80.0	100.0
	Change from baseline in overall work impairment due to health (%)	n	11	11
		Mean	-34.55	-23.84
		SD	36.447	39.997
		Median	-20.00	-24.00
		Min.	-86.9	-90.0
		Max.	20.0	44.6

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.64
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	104	94
		Mean	57.88	49.47
		SD	29.843	31.601
		Median	60.00	50.00
		Min.	0.0	10.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	81	88
		Mean	25.31	21.02
		SD	23.879	22.026
		Median	10.00	10.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in activity impairment due to health (%)	n	52	53
		Mean	-36.92	-32.83
		SD	34.671	41.342
		Median	-40.00	-20.00
		Min.	-100.0	-90.0
		Max.	50.0	70.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.64
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		206	212
Baseline	Work time missed due to health (%)	n	78	93
		Mean	54.83	61.39
		SD	38.878	39.591
		Median	62.26	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	32	39
		Mean	20.32	12.71
		SD	33.090	28.761
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in work time missed due to health (%)	n	24	30
		Mean	-21.17	-47.97
		SD	54.262	46.808
		Median	-6.16	-41.43
		Min.	-100.0	-100.0
		Max.	100.0	25.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.64
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	24	25
		Mean	59.58	42.40
		SD	29.114	28.178
		Median	60.00	40.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Impairment while working due to health (%)	n	24	25
		Mean	26.25	30.80
		SD	21.020	23.791
		Median	20.00	20.00
		Min.	0.0	10.0
		Max.	70.0	90.0
	Change from baseline in impairment while working due to health (%)	n	6	10
		Mean	-31.67	-11.00
		SD	50.365	23.310
		Median	-55.00	-5.00
		Min.	-80.0	-50.0
		Max.	50.0	20.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.64
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	24	25
		Mean	74.51	56.32
		SD	25.301	31.945
		Median	79.76	70.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Overall work impairment due to health (%)	n	24	25
		Mean	35.25	34.57
		SD	26.813	26.898
		Median	25.00	25.58
		Min.	0.0	10.0
		Max.	92.5	90.0
	Change from baseline in overall work impairment due to health (%)	n	6	10
		Mean	-31.03	-16.31
		SD	54.335	25.927
		Median	-48.17	-18.18
		Min.	-80.0	-56.4
		Max.	59.1	21.4

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.64
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	79	80
		Mean	66.84	62.38
		SD	25.598	29.947
		Median	70.00	70.00
		Min.	0.0	10.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	74	61
		Mean	30.00	30.82
		SD	26.380	27.282
		Median	20.00	20.00
		Min.	0.0	0.0
		Max.	100.0	90.0
	Change from baseline in activity impairment due to health (%)	n	39	33
		Mean	-29.49	-26.97
		SD	35.537	32.547
		Median	-40.00	-30.00
		Min.	-90.0	-80.0
		Max.	60.0	50.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.65
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Work time missed due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	231	234
n	28	41
LS Mean (SE)	4.66 (5.449)	13.80 (4.496)
95% C.I.	(-6.13, 15.45)	(4.89, 22.70)
LS Mean Change from Baseline (SE)	-43.77 (5.449)	-34.63 (4.496)
95% C.I.	(-54.56, -32.98)	(-43.53, -25.73)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		9.14 (7.052)
95% C.I.		(-4.83, 23.10)
p-value		0.198
Corrected Hedge’s g (SE) [1]		0.31 (0.247)
95% C.I.		(-0.17, 0.80)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.65
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Impairment while working due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	11	11
LS Mean (SE)	22.95 (5.300)	14.42 (5.382)
95% C.I.	(12.17, 33.73)	(3.47, 25.37)
LS Mean Change from Baseline (SE)	-21.79 (5.300)	-30.32 (5.382)
95% C.I.	(-32.57, -11.00)	(-41.27, -19.37)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-8.53 (7.518)
95% C.I.		(-23.83, 6.76)
p-value		0.264
Corrected Hedge’s g (SE) [1]		-0.46 (0.432)
95% C.I.		(-1.31, 0.38)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.65
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	11	11
LS Mean (SE)	22.69 (6.260)	20.22 (6.410)
95% C.I.	(9.95, 35.42)	(7.18, 33.26)
LS Mean Change from Baseline (SE)	-33.96 (6.260)	-36.43 (6.410)
95% C.I.	(-46.70, -21.22)	(-49.47, -23.38)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.46 (8.969)
95% C.I.		(-20.71, 15.78)
p-value		0.785
Corrected Hedge’s g (SE) [1]		-0.11 (0.427)
95% C.I.		(-0.95, 0.72)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: WPAI was scheduled for the Expansion phase only.

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Table 24.65
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity
Domain: Activity impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	52	53
LS Mean (SE)	25.03 (3.388)	20.91 (3.385)
95% C.I.	(18.34, 31.72)	(14.23, 27.59)
LS Mean Change from Baseline (SE)	-35.42 (3.388)	-39.54 (3.385)
95% C.I.	(-42.11, -28.73)	(-46.22, -32.86)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-4.12 (4.799)
95% C.I.		(-13.59, 5.35)
p-value		0.392
Corrected Hedge’s g (SE) [1]		-0.17 (0.196)
95% C.I.		(-0.55, 0.22)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.65
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Work time missed due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	206	212
n	24	30
LS Mean (SE)	22.32 (5.880)	13.70 (5.334)
95% C.I.	(10.68, 33.97)	(3.14, 24.26)
LS Mean Change from Baseline (SE)	-26.10 (5.880)	-34.72 (5.334)
95% C.I.	(-37.75, -14.46)	(-45.29, -24.16)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-8.62 (7.980)
95% C.I.		(-24.42, 7.18)
p-value		0.282
Corrected Hedge’s g (SE) [1]		-0.29 (0.275)
95% C.I.		(-0.83, 0.25)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.65
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Impairment while working due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	6	10
LS Mean (SE)	30.24 (7.385)	36.75 (5.560)
95% C.I.	(15.22, 45.27)	(25.44, 48.06)
LS Mean Change from Baseline (SE)	-14.50 (7.385)	-7.99 (5.560)
95% C.I.	(-29.52, 0.53)	(-19.30, 3.32)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		6.51 (9.183)
95% C.I.		(-12.18, 25.19)
p-value		0.483
Corrected Hedge’s g (SE) [1]		0.35 (0.520)
95% C.I.		(-0.67, 1.37)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.65
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	6	10
LS Mean (SE)	40.40 (8.629)	44.66 (6.582)
95% C.I.	(22.84, 57.95)	(31.27, 58.05)
LS Mean Change from Baseline (SE)	-16.25 (8.629)	-11.99 (6.582)
95% C.I.	(-33.81, 1.30)	(-25.38, 1.41)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		4.27 (10.782)
95% C.I.		(-17.67, 26.20)
p-value		0.695
Corrected Hedge’s g (SE) [1]		0.19 (0.518)
95% C.I.		(-0.82, 1.21)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.65
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity
Domain: Activity impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	39	33
LS Mean (SE)	35.65 (3.923)	36.36 (4.255)
95% C.I.	(27.91, 43.39)	(27.96, 44.76)
LS Mean Change from Baseline (SE)	-24.80 (3.923)	-24.09 (4.255)
95% C.I.	(-32.55, -17.06)	(-32.49, -15.70)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.71 (5.777)
95% C.I.		(-10.69, 12.11)
p-value		0.903
Corrected Hedge’s g (SE) [1]		0.03 (0.237)
95% C.I.		(-0.44, 0.49)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, patient reported symptom severity (<2, >=2), baseline and treatment by patient reported symptom severity interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Protocol: 214367
Population: Intent-to-Treat Data as of 27APR2021

Table 24.75
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: Europe

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		15	14
Baseline	Work time missed due to health (%)	n	5	5
		Mean	55.29	68.09
		SD	51.382	42.168
		Median	76.47	84.91
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	3	3
		Mean	33.33	18.52
		SD	57.735	32.075
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	100.0	55.6
	Change from baseline in work time missed due to health (%)	n	3	2
		Mean	7.84	-64.68
		SD	88.496	49.957
		Median	0.00	-64.68
		Min.	-76.5	-100.0
		Max.	100.0	-29.4

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.75
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: Europe

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	3	3
		Mean	63.33	40.00
		SD	28.868	30.000
		Median	80.00	40.00
		Min.	30.0	10.0
		Max.	80.0	70.0
Day 29	Impairment while working due to health (%)	n	2	3
		Mean	40.00	23.33
		SD	28.284	23.094
		Median	40.00	10.00
		Min.	20.0	10.0
		Max.	60.0	50.0
	Change from baseline in impairment while working due to health (%)	n	2	1
		Mean	-40.00	-20.00
		SD	28.284	
		Median	-40.00	-20.00
		Min.	-60.0	-20.0
		Max.	-20.0	-20.0

Note: WPAI was scheduled for the Expansion phase only.

Table 24.75
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: Europe

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	3	3
		Mean	68.43	59.60
		SD	34.150	44.360
		Median	80.00	73.33
		Min.	30.0	10.0
		Max.	95.3	95.5
Day 29	Overall work impairment due to health (%)	n	2	3
		Mean	40.00	32.59
		SD	28.284	39.132
		Median	40.00	10.00
		Min.	20.0	10.0
		Max.	60.0	77.8
	Change from baseline in overall work impairment due to health (%)	n	2	1
		Mean	-47.65	-17.69
		SD	39.099	
		Median	-47.65	-17.69
		Min.	-75.3	-17.7
		Max.	-20.0	-17.7

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.75
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: Europe

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	8	9
		Mean	62.50	40.00
		SD	28.661	28.723
		Median	70.00	40.00
		Min.	10.0	10.0
		Max.	90.0	80.0
Day 29	Activity impairment due to health (%)	n	5	7
		Mean	58.00	31.43
		SD	32.711	29.114
		Median	60.00	10.00
		Min.	10.0	10.0
		Max.	100.0	80.0
	Change from baseline in activity impairment due to health (%)	n	4	5
		Mean	-20.00	-22.00
		SD	8.165	48.683
		Median	-20.00	-30.00
		Min.	-30.0	-70.0
		Max.	-10.0	50.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.75
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: North America

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		502	503
Baseline	Work time missed due to health (%)	n	162	194
		Mean	52.15	56.12
		SD	38.717	39.803
		Median	53.29	55.56
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	83	102
		Mean	12.52	11.61
		SD	27.305	27.637
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in work time missed due to health (%)	n	52	70
		Mean	-34.34	-36.27
		SD	43.142	48.542
		Median	-23.10	-26.86
		Min.	-100.0	-100.0
		Max.	80.0	71.4

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.75
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: North America

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	56	58
		Mean	48.04	41.72
		SD	31.184	29.979
		Median	50.00	45.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Impairment while working due to health (%)	n	59	66
		Mean	23.39	24.24
		SD	18.533	23.275
		Median	20.00	10.00
		Min.	0.0	0.0
		Max.	80.0	100.0
	Change from baseline in impairment while working due to health (%)	n	14	21
		Mean	-18.57	-16.67
		SD	38.801	29.040
		Median	-10.00	0.00
		Min.	-80.0	-90.0
		Max.	50.0	20.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.75
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: North America

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	56	57
		Mean	64.41	53.71
		SD	29.846	32.141
		Median	67.21	64.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Overall work impairment due to health (%)	n	59	65
		Mean	28.50	27.95
		SD	23.413	25.477
		Median	20.00	20.00
		Min.	0.0	0.0
		Max.	92.5	100.0
	Change from baseline in overall work impairment due to health (%)	n	14	20
		Mean	-29.33	-18.67
		SD	44.026	34.415
		Median	-26.55	-14.33
		Min.	-86.9	-90.0
		Max.	59.1	44.6

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.75
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: North America

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	187	174
		Mean	61.71	56.09
		SD	28.872	31.544
		Median	70.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	170	167
		Mean	27.24	24.01
		SD	25.162	24.472
		Median	15.00	10.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in activity impairment due to health (%)	n	94	87
		Mean	-33.51	-32.18
		SD	35.642	35.908
		Median	-40.00	-30.00
		Min.	-100.0	-90.0
		Max.	60.0	70.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.75
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: South America

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
	Number of subjects in subgroup		12	11
Baseline	Work time missed due to health (%)	n	4	5
		Mean	34.72	67.71
		SD	44.531	41.740
		Median	19.44	81.40
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	1	2
		Mean	6.98	4.65
		SD		6.578
		Median	6.98	4.65
		Min.	7.0	0.0
		Max.	7.0	9.3
	Change from baseline in work time missed due to health (%)	n	1	2
		Mean	-15.25	-86.05
		SD		19.733
		Median	-15.25	-86.05
		Min.	-15.2	-100.0
		Max.	-15.2	-72.1

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.75
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: South America

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Impairment while working due to health (%)	n	3	2
		Mean	53.33	25.00
		SD	37.859	21.213
		Median	70.00	25.00
		Min.	10.0	10.0
		Max.	80.0	40.0
Day 29	Impairment while working due to health (%)	n	1	2
		Mean	10.00	30.00
		SD		28.284
		Median	10.00	30.00
		Min.	10.0	10.0
		Max.	10.0	50.0
	Change from baseline in impairment while working due to health (%)	n	1	1
		Mean	-60.00	10.00
		SD		
		Median	-60.00	10.00
		Min.	-60.0	10.0
		Max.	-60.0	10.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.75
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: South America

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Overall work impairment due to health (%)	n	3	2
		Mean	56.67	49.42
		SD	40.552	55.746
		Median	76.67	49.42
		Min.	10.0	10.0
		Max.	83.3	88.8
Day 29	Overall work impairment due to health (%)	n	1	2
		Mean	16.28	32.33
		SD		31.573
		Median	16.28	32.33
		Min.	16.3	10.0
		Max.	16.3	54.7
	Change from baseline in overall work impairment due to health (%)	n	1	1
		Mean	-60.39	-34.19
		SD		
		Median	-60.39	-34.19
		Min.	-60.4	-34.2
		Max.	-60.4	-34.2

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.75
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: South America

Visit			Placebo (N=529)	VIR-7831 500mg (N=528)
Baseline	Activity impairment due to health (%)	n	6	6
		Mean	40.00	41.67
		SD	29.665	31.885
		Median	35.00	35.00
		Min.	10.0	10.0
		Max.	80.0	80.0
Day 29	Activity impairment due to health (%)	n	3	3
		Mean	23.33	43.33
		SD	15.275	35.119
		Median	20.00	40.00
		Min.	10.0	10.0
		Max.	40.0	80.0
	Change from baseline in activity impairment due to health (%)	n	2	3
		Mean	-30.00	16.67
		SD	14.142	47.258
		Median	-30.00	0.00
		Min.	-40.0	-20.0
		Max.	-20.0	70.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.76
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: Europe
Domain: Work time missed due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	15	14
n	3	2
LS Mean (SE)	35.78 (17.133)	23.23 (21.089)
95% C.I.	(1.87, 69.70)	(-18.52, 64.97)
LS Mean Change from Baseline (SE)	-13.14 (17.133)	-25.70 (21.089)
95% C.I.	(-47.05, 20.77)	(-67.44, 16.05)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-12.56 (27.327)
95% C.I.		(-66.65, 41.54)
p-value		0.647
Corrected Hedge’s g (SE) [1]		-0.31 (0.918)
95% C.I.		(-2.11, 1.49)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.76
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: Europe
Domain: Impairment while working due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	2	1
LS Mean (SE)	35.00 (13.749)	46.39 (18.936)
95% C.I.	(7.02, 62.97)	(7.86, 84.91)
LS Mean Change from Baseline (SE)	-9.00 (13.749)	2.39 (18.936)
95% C.I.	(-36.98, 18.97)	(-36.14, 40.91)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		11.39 (22.990)
95% C.I.		(-35.38, 58.16)
p-value		0.624
Corrected Hedge’s g (SE) [1]		0.00 (1.225)
95% C.I.		(-2.40, 2.40)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.76
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: Europe
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	2	1
LS Mean (SE)	36.93 (16.331)	73.97 (22.963)
95% C.I.	(3.67, 70.20)	(27.19, 120.74)
LS Mean Change from Baseline (SE)	-18.26 (16.331)	18.77 (22.963)
95% C.I.	(-51.53, 15.00)	(-28.00, 65.55)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		37.04 (27.588)
95% C.I.		(-19.16, 93.23)
p-value		0.189
Corrected Hedge’s g (SE) [1]		0.00 (1.225)
95% C.I.		(-2.40, 2.40)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.76
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: Europe
Domain: Activity impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	4	5
LS Mean (SE)	46.18 (12.560)	27.95 (11.247)
95% C.I.	(21.40, 70.96)	(5.77, 50.14)
LS Mean Change from Baseline (SE)	-13.46 (12.560)	-31.69 (11.247)
95% C.I.	(-38.24, 11.32)	(-53.87, -9.50)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-18.23 (16.879)
95% C.I.		(-51.52, 15.07)
p-value		0.282
Corrected Hedge’s g (SE) [1]		-0.64 (0.688)
95% C.I.		(-1.99, 0.70)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.76
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: North America
Domain: Work time missed due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	502	503
n	52	70
LS Mean (SE)	12.45 (4.102)	13.30 (3.533)
95% C.I.	(4.33, 20.57)	(6.31, 20.30)
LS Mean Change from Baseline (SE)	-36.47 (4.102)	-35.62 (3.533)
95% C.I.	(-44.59, -28.35)	(-42.62, -28.63)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		0.85 (5.415)
95% C.I.		(-9.87, 11.57)
p-value		0.876
Corrected Hedge’s g (SE) [1]		0.03 (0.183)
95% C.I.		(-0.33, 0.39)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: WPAI was scheduled for the Expansion phase only.

Table 24.76
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: North America
Domain: Impairment while working due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	14	21
LS Mean (SE)	25.06 (5.012)	22.66 (4.129)
95% C.I.	(14.86, 35.26)	(14.26, 31.06)
LS Mean Change from Baseline (SE)	-18.94 (5.012)	-21.34 (4.129)
95% C.I.	(-29.14, -8.74)	(-29.74, -12.94)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.40 (6.490)
95% C.I.		(-15.60, 10.80)
p-value		0.714
Corrected Hedge’s g (SE) [1]		-0.12 (0.345)
95% C.I.		(-0.80, 0.55)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.76
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: North America
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	14	20
LS Mean (SE)	28.45 (6.026)	27.46 (5.158)
95% C.I.	(16.18, 40.72)	(16.95, 37.96)
LS Mean Change from Baseline (SE)	-26.74 (6.026)	-27.74 (5.158)
95% C.I.	(-39.02, -14.47)	(-38.25, -17.23)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-0.99 (7.977)
95% C.I.		(-17.24, 15.26)
p-value		0.902
Corrected Hedge’s g (SE) [1]		-0.04 (0.349)
95% C.I.		(-0.73, 0.64)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.76
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: North America
Domain: Activity impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	94	87
LS Mean (SE)	28.38 (2.594)	26.32 (2.693)
95% C.I.	(23.26, 33.49)	(21.01, 31.63)
LS Mean Change from Baseline (SE)	-31.26 (2.594)	-33.32 (2.693)
95% C.I.	(-36.38, -26.15)	(-38.63, -28.01)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-2.06 (3.742)
95% C.I.		(-9.44, 5.33)
p-value		0.583
Corrected Hedge’s g (SE) [1]		-0.08 (0.149)
95% C.I.		(-0.37, 0.21)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.76
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: South America
Domain: Work time missed due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
Number of subjects in subgroup	12	11
n	1	2
LS Mean (SE)	9.77 (29.610)	0.28 (21.075)
95% C.I.	(-48.84, 68.38)	(-41.43, 42.00)
LS Mean Change from Baseline (SE)	-39.16 (29.610)	-48.64 (21.075)
95% C.I.	(-97.77, 19.46)	(-90.36, -6.93)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		-9.49 (36.471)
95% C.I.		(-81.68, 62.71)
p-value		0.795
Corrected Hedge’s g (SE) [1]		0.00 (1.225)
95% C.I.		(-2.40, 2.40)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.76
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: South America
Domain: Impairment while working due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	1	1

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.76
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: South America
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	1	1

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 24.76
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Region

Region: South America
Domain: Activity impairment due to health (%)

	Placebo (N=529)	VIR-7831 500mg (N=528)
n	2	3
LS Mean (SE)	25.78 (17.752)	48.87 (14.624)
95% C.I.	(-9.24, 60.80)	(20.02, 77.72)
LS Mean Change from Baseline (SE)	-33.86 (17.752)	-10.77 (14.624)
95% C.I.	(-68.88, 1.16)	(-39.62, 18.08)
VIR-7831 500 mg vs. Placebo		
Difference (SE)		23.09 (22.977)
95% C.I.		(-22.23, 68.42)
p-value		0.316
Corrected Hedge’s g (SE) [1]		0.66 (0.937)
95% C.I.		(-1.17, 2.50)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), baseline and treatment by region interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 23.10
Summary and Analysis of Proportion of Subjects with Adverse Events by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	470	468
Any event	109 (23.2%)	98 (20.9%)
Odds Ratio		0.88
95% CI		(0.64, 1.19)
Relative Risk		0.90
95% CI		(0.71, 1.15)
Risk Difference (%)		-2.25
95% CI		(-7.56, 3.05)
p-value [1]		0.431

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.10
Summary and Analysis of Proportion of Subjects with Adverse Events by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	34 (7.2%)	12 (2.6%)
Odds Ratio		0.34
95% CI		(0.17, 0.66)
Relative Risk		0.35
95% CI		(0.19, 0.68)
Risk Difference (%)		-4.67
95% CI		(-7.42, -1.92)
p-value [1]		0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.10
Summary and Analysis of Proportion of Subjects with Adverse Events by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	19 (4.0%)	3 (0.6%)
Odds Ratio		0.15
95% CI		(0.03, 0.53)
Relative Risk		0.16
95% CI		(0.05, 0.53)
Risk Difference (%)		-3.40
95% CI		(-5.32, -1.48)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.10
Summary and Analysis of Proportion of Subjects with Adverse Events by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	56	55
Any event	14 (25.0%)	16 (29.1%)
Odds Ratio		1.23
95% CI		(0.53, 2.85)
Relative Risk		1.16
95% CI		(0.63, 2.15)
Risk Difference (%)		4.09
95% CI		(-12.42, 20.60)
p-value [1]		0.673

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.10
Summary and Analysis of Proportion of Subjects with Adverse Events by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	9 (16.1%)	4 (7.3%)
Odds Ratio		0.41
95% CI		(0.12, 1.42)
Relative Risk		0.45
95% CI		(0.15, 1.38)
Risk Difference (%)		-8.80
95% CI		(-20.62, 3.02)
p-value [1]		0.237

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.10
Summary and Analysis of Proportion of Subjects with Adverse Events by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	3 (5.4%)	2 (3.6%)
Odds Ratio		0.67
95% CI		(0.11, 4.15)
Relative Risk		0.68
95% CI		(0.12, 3.91)
Risk Difference (%)		-1.72
95% CI		(-9.42, 5.98)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.11
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	470	468
Any event	24 (5.1%)	7 (1.5%)
Odds Ratio		0.28
95% CI		(0.10, 0.68)
Relative Risk		0.29
95% CI		(0.13, 0.67)
Risk Difference (%)		-3.61
95% CI		(-5.88, -1.34)
p-value [1]		0.003

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.11
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	20 (4.3%)	2 (0.4%)
Odds Ratio		0.10
95% CI		(0.01, 0.40)
Relative Risk		0.10
95% CI		(0.02, 0.43)
Risk Difference (%)		-3.83
95% CI		(-5.75, -1.91)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.11
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	17 (3.6%)	1 (0.2%)
Odds Ratio		0.06
95% CI		(0.00, 0.37)
Relative Risk		0.06
95% CI		(0.01, 0.44)
Risk Difference (%)		-3.40
95% CI		(-5.14, -1.66)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.11
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	56	55
Any event	8 (14.3%)	4 (7.3%)
Odds Ratio		0.47
95% CI		(0.13, 1.66)
Relative Risk		0.51
95% CI		(0.16, 1.59)
Risk Difference (%)		-7.01
95% CI		(-18.46, 4.44)
p-value [1]		0.360

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.11
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	5 (8.9%)	3 (5.5%)
Odds Ratio		0.59
95% CI		(0.13, 2.59)
Relative Risk		0.61
95% CI		(0.15, 2.43)
Risk Difference (%)		-3.47
95% CI		(-13.06, 6.11)
p-value [1]		0.716

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.11
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	3 (5.4%)	2 (3.6%)
Odds Ratio		0.67
95% CI		(0.11, 4.15)
Relative Risk		0.68
95% CI		(0.12, 3.91)
Risk Difference (%)		-1.72
95% CI		(-9.42, 5.98)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.12
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	470	468
Any event	2 (0.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.12
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	56	55
Any event	2 (3.6%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.13
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Age Group (<=70, >70)

Age group (years): <=70

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	470	468
Any event	5 (1.1%)	5 (1.1%)
Odds Ratio		1.00
95% CI		(0.23, 4.40)
Relative Risk		1.00
95% CI		(0.29, 3.45)
Risk Difference (%)		0.00
95% CI		(-1.31, 1.32)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.13
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Age Group (<=70, >70)

Age group (years): >70

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	56	55
Any event	1 (1.8%)	1 (1.8%)
Odds Ratio		1.02
95% CI		(0.01, 81.39)
Relative Risk		1.02
95% CI		(0.07, 15.87)
Risk Difference (%)		0.03
95% CI		(-4.92, 4.98)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.14
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Age Group (<=70, >70)

Age group (years): <=70

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	470	468
Any event	0	1 (0.2%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 23.14
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Age Group (<=70, >70)

Age group (years): >70

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	56	55
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Protocol: 214367
Population: Safety Data as of 27APR2021

Table 23.15
Summary and Analysis of Proportion of Subjects with Serious Infusion-Related Reactions including Hypersensitivity by Age Group (<=70, >70)

No data to report

Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.16
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Age Group (<=70, >70)

Age group (years): <=70

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	470	468
Any event	0	1 (0.2%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 23.16
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Age Group (<=70, >70)

Age group (years): >70

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	56	55
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 23.17
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	470	468
Any event	1 (0.2%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.17
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	56	55
Any event	3 (5.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.18
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	470	468
Any event	23 (4.9%)	7 (1.5%)
Odds Ratio		0.30
95% CI		(0.11, 0.72)
Relative Risk		0.31
95% CI		(0.13, 0.71)
Risk Difference (%)		-3.40
95% CI		(-5.64, -1.16)
p-value [1]		0.005

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.18
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	19 (4.0%)	2 (0.4%)
Odds Ratio		0.10
95% CI		(0.01, 0.43)
Relative Risk		0.11
95% CI		(0.02, 0.45)
Risk Difference (%)		-3.62
95% CI		(-5.49, -1.74)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.18
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	17 (3.6%)	1 (0.2%)
Odds Ratio		0.06
95% CI		(0.00, 0.37)
Relative Risk		0.06
95% CI		(0.01, 0.44)
Risk Difference (%)		-3.40
95% CI		(-5.14, -1.66)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.18
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	56	55
Any event	6 (10.7%)	4 (7.3%)
Odds Ratio		0.65
95% CI		(0.17, 2.46)
Relative Risk		0.68
95% CI		(0.20, 2.27)
Risk Difference (%)		-3.44
95% CI		(-14.06, 7.18)
p-value [1]		0.742

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.18
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	3 (5.4%)	3 (5.5%)
Odds Ratio		1.02
95% CI		(0.20, 5.28)
Relative Risk		1.02
95% CI		(0.21, 4.83)
Risk Difference (%)		0.10
95% CI		(-8.32, 8.51)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.18
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	1 (1.8%)	2 (3.6%)
Odds Ratio		2.08
95% CI		(0.10, 124.64)
Relative Risk		2.04
95% CI		(0.19, 21.82)
Risk Difference (%)		1.85
95% CI		(-4.19, 7.89)
p-value [1]		0.618

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	96	98
Any event	20 (20.8%)	21 (21.4%)
Odds Ratio		1.04
95% CI		(0.52, 2.07)
Relative Risk		1.03
95% CI		(0.60, 1.77)
Risk Difference (%)		0.60
95% CI		(-10.89, 12.08)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	2 (2.1%)	4 (4.1%)
Odds Ratio		2.00
95% CI		(0.36, 11.18)
Relative Risk		1.96
95% CI		(0.37, 10.45)
Risk Difference (%)		2.00
95% CI		(-2.85, 6.85)
p-value [1]		0.683

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	0	1 (1.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		1.02
95% CI		(-0.97, 3.01)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	84	72
Any event	16 (19.0%)	19 (26.4%)
Odds Ratio		1.52
95% CI		(0.72, 3.24)
Relative Risk		1.39
95% CI		(0.77, 2.49)
Risk Difference (%)		7.34
95% CI		(-5.86, 20.54)
p-value [1]		0.337

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	7 (8.3%)	4 (5.6%)
Odds Ratio		0.65
95% CI		(0.18, 2.31)
Relative Risk		0.67
95% CI		(0.20, 2.19)
Risk Difference (%)		-2.78
95% CI		(-10.71, 5.15)
p-value [1]		0.548

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	0	1 (1.4%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		1.39
95% CI		(-1.31, 4.09)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	58	64
Any event	18 (31.0%)	16 (25.0%)
Odds Ratio		0.74
95% CI		(0.34, 1.64)
Relative Risk		0.81
95% CI		(0.45, 1.43)
Risk Difference (%)		-6.03
95% CI		(-21.98, 9.91)
p-value [1]		0.545

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	7 (12.1%)	2 (3.1%)
Odds Ratio		0.24
95% CI		(0.05, 1.18)
Relative Risk		0.26
95% CI		(0.06, 1.20)
Risk Difference (%)		-8.94
95% CI		(-18.35, 0.46)
p-value [1]		0.084

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	4 (6.9%)	1 (1.6%)
Odds Ratio		0.21
95% CI		(0.00, 2.28)
Relative Risk		0.23
95% CI		(0.03, 1.97)
Risk Difference (%)		-5.33
95% CI		(-12.53, 1.86)
p-value [1]		0.190

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	60	73
Any event	17 (28.3%)	13 (17.8%)
Odds Ratio		0.55
95% CI		(0.24, 1.25)
Relative Risk		0.63
95% CI		(0.33, 1.19)
Risk Difference (%)		-10.53
95% CI		(-24.91, 3.86)
p-value [1]		0.211

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	6 (10.0%)	1 (1.4%)
Odds Ratio		0.13
95% CI		(0.00, 1.09)
Relative Risk		0.14
95% CI		(0.02, 1.11)
Risk Difference (%)		-8.63
95% CI		(-16.68, -0.58)
p-value [1]		0.046

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (3.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.33
95% CI		(-7.88, 1.21)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	181	160
Any event	44 (24.3%)	29 (18.1%)
Odds Ratio		0.69
95% CI		(0.41, 1.17)
Relative Risk		0.75
95% CI		(0.49, 1.13)
Risk Difference (%)		-6.18
95% CI		(-14.83, 2.46)
p-value [1]		0.187

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	18 (9.9%)	4 (2.5%)
Odds Ratio		0.23
95% CI		(0.08, 0.70)
Relative Risk		0.25
95% CI		(0.09, 0.73)
Risk Difference (%)		-7.44
95% CI		(-12.43, -2.46)
p-value [1]		0.007

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	13 (7.2%)	2 (1.3%)
Odds Ratio		0.16
95% CI		(0.02, 0.74)
Relative Risk		0.17
95% CI		(0.04, 0.76)
Risk Difference (%)		-5.93
95% CI		(-10.07, -1.80)
p-value [1]		0.008

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	96	98
Any event	0	2 (2.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		2.04
95% CI		(-0.76, 4.84)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	0	2 (2.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		2.04
95% CI		(-0.76, 4.84)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	0	1 (1.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		1.02
95% CI		(-0.97, 3.01)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	84	72
Any event	3 (3.6%)	1 (1.4%)
Odds Ratio		0.38
95% CI		(0.01, 4.88)
Relative Risk		0.39
95% CI		(0.04, 3.66)
Risk Difference (%)		-2.18
95% CI		(-6.98, 2.62)
p-value [1]		0.625

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	2 (2.4%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-2.38
95% CI		(-5.64, 0.88)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	58	64
Any event	5 (8.6%)	1 (1.6%)
Odds Ratio		0.17
95% CI		(0.00, 1.59)
Relative Risk		0.18
95% CI		(0.02, 1.51)
Risk Difference (%)		-7.06
95% CI		(-14.89, 0.78)
p-value [1]		0.101

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	5 (8.6%)	1 (1.6%)
Odds Ratio		0.17
95% CI		(0.00, 1.59)
Relative Risk		0.18
95% CI		(0.02, 1.51)
Risk Difference (%)		-7.06
95% CI		(-14.89, 0.78)
p-value [1]		0.101

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	4 (6.9%)	1 (1.6%)
Odds Ratio		0.21
95% CI		(0.00, 2.28)
Relative Risk		0.23
95% CI		(0.03, 1.97)
Risk Difference (%)		-5.33
95% CI		(-12.53, 1.86)
p-value [1]		0.190

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	60	73
Any event	3 (5.0%)	1 (1.4%)
Odds Ratio		0.26
95% CI		(0.00, 3.42)
Relative Risk		0.27
95% CI		(0.03, 2.57)
Risk Difference (%)		-3.63
95% CI		(-9.76, 2.50)
p-value [1]		0.327

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	2 (3.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.33
95% CI		(-7.88, 1.21)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (3.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.33
95% CI		(-7.88, 1.21)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	181	160
Any event	18 (9.9%)	4 (2.5%)
Odds Ratio		0.23
95% CI		(0.08, 0.70)
Relative Risk		0.25
95% CI		(0.09, 0.73)
Risk Difference (%)		-7.44
95% CI		(-12.43, -2.46)
p-value [1]		0.007

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	13 (7.2%)	2 (1.3%)
Odds Ratio		0.16
95% CI		(0.02, 0.74)
Relative Risk		0.17
95% CI		(0.04, 0.76)
Risk Difference (%)		-5.93
95% CI		(-10.07, -1.80)
p-value [1]		0.008

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	11 (6.1%)	1 (0.6%)
Odds Ratio		0.10
95% CI		(0.00, 0.69)
Relative Risk		0.10
95% CI		(0.01, 0.79)
Risk Difference (%)		-5.45
95% CI		(-9.14, -1.76)
p-value [1]		0.007

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.21
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	96	98
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.21
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	84	72
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.21
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	58	64
Any event	1 (1.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.21
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	60	73
Any event	1 (1.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.21
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	181	160
Any event	2 (1.1%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.22
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	96	98
Any event	0	2 (2.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

Table 23.22
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	84	72
Any event	1 (1.2%)	1 (1.4%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.22
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	58	64
Any event	0	1 (1.6%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.22
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	60	73
Any event	3 (5.0%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.22
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	181	160
Any event	2 (1.1%)	1 (0.6%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

Table 23.23
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Baseline Viral Load

No data to report

Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Protocol: 214367
Population: Safety Data as of 27APR2021

Table 23.24
Summary and Analysis of Proportion of Subjects with Serious Infusion-Related Reactions including Hypersensitivity by Baseline Viral Load

No data to report

Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.25
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Baseline Viral Load

No data to report

Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 23.26
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	96	98
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.26
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	84	72
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.26
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	58	64
Any event	1 (1.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.26
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	60	73
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.26
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	181	160
Any event	3 (1.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	96	98
Any event	0	2 (2.0%)
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		2.04 (-0.76, 4.84)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	0	2 (2.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		2.04
95% CI		(-0.76, 4.84)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	0	1 (1.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		1.02
95% CI		(-0.97, 3.01)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	84	72
Any event	3 (3.6%)	1 (1.4%)
Odds Ratio		0.38
95% CI		(0.01, 4.88)
Relative Risk		0.39
95% CI		(0.04, 3.66)
Risk Difference (%)		-2.18
95% CI		(-6.98, 2.62)
p-value [1]		0.625

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	2 (2.4%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-2.38
95% CI		(-5.64, 0.88)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	58	64
Any event	4 (6.9%)	1 (1.6%)
Odds Ratio		0.21
95% CI		(0.00, 2.28)
Relative Risk		0.23
95% CI		(0.03, 1.97)
Risk Difference (%)		-5.33
95% CI		(-12.53, 1.86)
p-value [1]		0.190

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	4 (6.9%)	1 (1.6%)
Odds Ratio		0.21
95% CI		(0.00, 2.28)
Relative Risk		0.23
95% CI		(0.03, 1.97)
Risk Difference (%)		-5.33
95% CI		(-12.53, 1.86)
p-value [1]		0.190

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	3 (5.2%)	1 (1.6%)
Odds Ratio		0.29
95% CI		(0.01, 3.78)
Relative Risk		0.30
95% CI		(0.03, 2.82)
Risk Difference (%)		-3.61
95% CI		(-10.07, 2.85)
p-value [1]		0.345

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	60	73
Any event	3 (5.0%)	1 (1.4%)
Odds Ratio		0.26
95% CI		(0.00, 3.42)
Relative Risk		0.27
95% CI		(0.03, 2.57)
Risk Difference (%)		-3.63
95% CI		(-9.76, 2.50)
p-value [1]		0.327

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	2 (3.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.33
95% CI		(-7.88, 1.21)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (3.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.33
95% CI		(-7.88, 1.21)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	181	160
Any event	16 (8.8%)	4 (2.5%)
Odds Ratio		0.26
95% CI		(0.09, 0.81)
Relative Risk		0.28
95% CI		(0.10, 0.83)
Risk Difference (%)		-6.34
95% CI		(-11.13, -1.55)
p-value [1]		0.019

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	11 (6.1%)	2 (1.3%)
Odds Ratio		0.20
95% CI		(0.02, 0.92)
Relative Risk		0.21
95% CI		(0.05, 0.91)
Risk Difference (%)		-4.83
95% CI		(-8.71, -0.94)
p-value [1]		0.023

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	10 (5.5%)	1 (0.6%)
Odds Ratio		0.11
95% CI		(0.00, 0.77)
Relative Risk		0.11
95% CI		(0.01, 0.87)
Risk Difference (%)		-4.90
95% CI		(-8.45, -1.35)
p-value [1]		0.012

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.28
Summary and Analysis of Proportion of Subjects with Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	255	228
Any event	62 (24.3%)	38 (16.7%)
Odds Ratio		0.62
95% CI		(0.40, 0.98)
Relative Risk		0.69
95% CI		(0.48, 0.98)
Risk Difference (%)		-7.65
95% CI		(-14.80, -0.50)
p-value [1]		0.043

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.28
Summary and Analysis of Proportion of Subjects with Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	20 (7.8%)	10 (4.4%)
Odds Ratio		0.54
95% CI		(0.25, 1.18)
Relative Risk		0.56
95% CI		(0.27, 1.17)
Risk Difference (%)		-3.46
95% CI		(-7.69, 0.78)
p-value [1]		0.133

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.28
Summary and Analysis of Proportion of Subjects with Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	13 (5.1%)	3 (1.3%)
Odds Ratio		0.25
95% CI		(0.04, 0.92)
Relative Risk		0.26
95% CI		(0.07, 0.89)
Risk Difference (%)		-3.78
95% CI		(-6.86, -0.70)
p-value [1]		0.022

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.28
Summary and Analysis of Proportion of Subjects with Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	271	295
Any event	61 (22.5%)	76 (25.8%)
Odds Ratio		1.19
95% CI		(0.81, 1.76)
Relative Risk		1.14
95% CI		(0.85, 1.54)
Risk Difference (%)		3.25
95% CI		(-3.79, 10.30)
p-value [1]		0.378

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.28
Summary and Analysis of Proportion of Subjects with Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	23 (8.5%)	6 (2.0%)
Odds Ratio		0.22
95% CI		(0.09, 0.56)
Relative Risk		0.24
95% CI		(0.10, 0.58)
Risk Difference (%)		-6.45
95% CI		(-10.14, -2.76)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.28
Summary and Analysis of Proportion of Subjects with Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	9 (3.3%)	2 (0.7%)
Odds Ratio		0.20
95% CI		(0.02, 0.97)
Relative Risk		0.20
95% CI		(0.04, 0.94)
Risk Difference (%)		-2.64
95% CI		(-4.97, -0.31)
p-value [1]		0.031

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.29
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	255	228
Any event	18 (7.1%)	6 (2.6%)
Odds Ratio		0.36
95% CI		(0.14, 0.91)
Relative Risk		0.37
95% CI		(0.15, 0.92)
Risk Difference (%)		-4.43
95% CI		(-8.20, -0.66)
p-value [1]		0.034

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.29
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	14 (5.5%)	3 (1.3%)
Odds Ratio		0.23
95% CI		(0.04, 0.84)
Relative Risk		0.24
95% CI		(0.07, 0.82)
Risk Difference (%)		-4.17
95% CI		(-7.34, -1.01)
p-value [1]		0.013

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.29
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	11 (4.3%)	2 (0.9%)
Odds Ratio		0.20
95% CI		(0.02, 0.92)
Relative Risk		0.20
95% CI		(0.05, 0.91)
Risk Difference (%)		-3.44
95% CI		(-6.21, -0.66)
p-value [1]		0.023

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.29
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	271	295
Any event	14 (5.2%)	5 (1.7%)
Odds Ratio		0.32
95% CI		(0.09, 0.95)
Relative Risk		0.33
95% CI		(0.12, 0.90)
Risk Difference (%)		-3.47
95% CI		(-6.49, -0.45)
p-value [1]		0.033

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.29
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	11 (4.1%)	2 (0.7%)
Odds Ratio		0.16
95% CI		(0.02, 0.75)
Relative Risk		0.17
95% CI		(0.04, 0.75)
Risk Difference (%)		-3.38
95% CI		(-5.91, -0.85)
p-value [1]		0.009

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.29
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	9 (3.3%)	1 (0.3%)
Odds Ratio		0.10
95% CI		(0.00, 0.73)
Relative Risk		0.10
95% CI		(0.01, 0.80)
Risk Difference (%)		-2.98
95% CI		(-5.22, -0.75)
p-value [1]		0.008

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.30
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	255	228
Any event	2 (0.8%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.30
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	271	295
Any event	2 (0.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.31
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Gender

Gender: Male

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	255	228
Any event	3 (1.2%)	2 (0.9%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

Table 23.31
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Gender

Gender: Female

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	271	295
Any event	3 (1.1%)	4 (1.4%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.32

Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Gender

Gender: Male

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	255	228
Any event	0	1 (0.4%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Table 23.32
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Gender

Gender: Female

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	271	295
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Protocol: 214367
Population: Safety Data as of 27APR2021

Table 23.33
Summary and Analysis of Proportion of Subjects with Serious Infusion-Related Reactions including Hypersensitivity by Gender

No data to report

Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.34
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Gender

Gender: Male

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	255	228
Any event	0	1 (0.4%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 23.34
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Gender

Gender: Female

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	271	295
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 23.35
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	255	228
Any event	3 (1.2%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.35
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	271	295
Any event	1 (0.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.36
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	255	228
Any event	16 (6.3%)	6 (2.6%)
Odds Ratio		0.40
95% CI		(0.16, 1.05)
Relative Risk		0.42
95% CI		(0.17, 1.05)
Risk Difference (%)		-3.64
95% CI		(-7.27, -0.01)
p-value [1]		0.079

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.36
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	12 (4.7%)	3 (1.3%)
Odds Ratio		0.27
95% CI		(0.05, 1.02)
Relative Risk		0.28
95% CI		(0.08, 0.98)
Risk Difference (%)		-3.39
95% CI		(-6.38, -0.40)
p-value [1]		0.037

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.36
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	10 (3.9%)	2 (0.9%)
Odds Ratio		0.22
95% CI		(0.02, 1.04)
Relative Risk		0.22
95% CI		(0.05, 1.01)
Risk Difference (%)		-3.04
95% CI		(-5.72, -0.37)
p-value [1]		0.040

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.36
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	271	295
Any event	13 (4.8%)	5 (1.7%)
Odds Ratio		0.34
95% CI		(0.09, 1.04)
Relative Risk		0.35
95% CI		(0.13, 0.98)
Risk Difference (%)		-3.10
95% CI		(-6.04, -0.16)
p-value [1]		0.053

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.36
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	10 (3.7%)	2 (0.7%)
Odds Ratio		0.18
95% CI		(0.02, 0.85)
Relative Risk		0.18
95% CI		(0.04, 0.83)
Risk Difference (%)		-3.01
95% CI		(-5.44, -0.58)
p-value [1]		0.017

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.36
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	8 (3.0%)	1 (0.3%)
Odds Ratio		0.11
95% CI		(0.00, 0.85)
Relative Risk		0.11
95% CI		(0.01, 0.91)
Risk Difference (%)		-2.61
95% CI		(-4.73, -0.49)
p-value [1]		0.016

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	306	290
Any event	67 (21.9%)	59 (20.3%)
Odds Ratio		0.91
95% CI		(0.61, 1.35)
Relative Risk		0.93
95% CI		(0.68, 1.27)
Risk Difference (%)		-1.55
95% CI		(-8.10, 5.00)
p-value [1]		0.688

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	21 (6.9%)	3 (1.0%)
Odds Ratio		0.14
95% CI		(0.03, 0.48)
Relative Risk		0.15
95% CI		(0.05, 0.50)
Risk Difference (%)		-5.83
95% CI		(-8.89, -2.77)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	10 (3.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.27
95% CI		(-5.26, -1.28)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	151	176
Any event	35 (23.2%)	41 (23.3%)
Odds Ratio		1.01
95% CI		(0.60, 1.68)
Relative Risk		1.01
95% CI		(0.68, 1.49)
Risk Difference (%)		0.12
95% CI		(-9.06, 9.30)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	12 (7.9%)	8 (4.5%)
Odds Ratio		0.55
95% CI		(0.22, 1.39)
Relative Risk		0.57
95% CI		(0.24, 1.36)
Risk Difference (%)		-3.40
95% CI		(-8.70, 1.90)
p-value [1]		0.249

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	7 (4.6%)	3 (1.7%)
Odds Ratio		0.36
95% CI		(0.06, 1.60)
Relative Risk		0.37
95% CI		(0.10, 1.40)
Risk Difference (%)		-2.93
95% CI		(-6.79, 0.93)
p-value [1]		0.196

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	69	57
Any event	21 (30.4%)	14 (24.6%)
Odds Ratio		0.74
95% CI		(0.34, 1.64)
Relative Risk		0.81
95% CI		(0.45, 1.44)
Risk Difference (%)		-5.87
95% CI		(-21.45, 9.71)
p-value [1]		0.550

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	10 (14.5%)	5 (8.8%)
Odds Ratio		0.57
95% CI		(0.18, 1.77)
Relative Risk		0.61
95% CI		(0.22, 1.67)
Risk Difference (%)		-5.72
95% CI		(-16.81, 5.37)
p-value [1]		0.412

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	5 (7.2%)	2 (3.5%)
Odds Ratio		0.47
95% CI		(0.09, 2.49)
Relative Risk		0.48
95% CI		(0.10, 2.40)
Risk Difference (%)		-3.74
95% CI		(-11.50, 4.02)
p-value [1]		0.455

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.38

Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	306	290
Any event	17 (5.6%)	2 (0.7%)
Odds Ratio		0.12
95% CI		(0.01, 0.51)
Relative Risk		0.12
95% CI		(0.03, 0.53)
Risk Difference (%)		-4.87
95% CI		(-7.60, -2.13)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.38
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	10 (3.3%)	1 (0.3%)
Odds Ratio		0.10
95% CI		(0.00, 0.73)
Relative Risk		0.11
95% CI		(0.01, 0.82)
Risk Difference (%)		-2.92
95% CI		(-5.03, -0.82)
p-value [1]		0.011

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.38
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	9 (2.9%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.38
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	151	176
Any event	9 (6.0%)	4 (2.3%)
Odds Ratio		0.37
95% CI		(0.11, 1.22)
Relative Risk		0.38
95% CI		(0.12, 1.21)
Risk Difference (%)		-3.69
95% CI		(-8.06, 0.68)
p-value [1]		0.153

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.38
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	9 (6.0%)	2 (1.1%)
Odds Ratio		0.18
95% CI		(0.02, 0.90)
Relative Risk		0.19
95% CI		(0.04, 0.87)
Risk Difference (%)		-4.82
95% CI		(-8.91, -0.74)
p-value [1]		0.027

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.38
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	7 (4.6%)	1 (0.6%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.38
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	69	57
Any event	6 (8.7%)	5 (8.8%)
Odds Ratio		1.01
95% CI		(0.29, 3.50)
Relative Risk		1.01
95% CI		(0.32, 3.13)
Risk Difference (%)		0.08
95% CI		(-9.83, 9.98)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.38
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	6 (8.7%)	2 (3.5%)
Odds Ratio		0.38
95% CI		(0.07, 1.97)
Relative Risk		0.40
95% CI		(0.08, 1.92)
Risk Difference (%)		-5.19
95% CI		(-13.37, 3.00)
p-value [1]		0.292

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.38
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	4 (5.8%)	2 (3.5%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.39
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	306	290
Any event	1 (0.3%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.39
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	151	176
Any event	2 (1.3%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.39
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	69	57
Any event	1 (1.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.40
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Number of Risk Factors

Number of risk factors: <=1

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	306	290
Any event	4 (1.3%)	2 (0.7%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.40
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Number of Risk Factors

Number of risk factors: 2

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	151	176
Any event	1 (0.7%)	2 (1.1%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

Table 23.40
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Number of Risk Factors

Number of risk factors: >=3

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	69	57
Any event	1 (1.4%)	2 (3.5%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

Table 23.41
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Number of Risk Factors

Number of risk factors: <=1

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	306	290
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 23.41
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Number of Risk Factors

Number of risk factors: 2

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	151	176
Any event	0	1 (0.6%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 23.41
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Number of Risk Factors

Number of risk factors: >=3

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	69	57
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Protocol: 214367
Population: Safety Data as of 27APR2021

Table 23.42
Summary and Analysis of Proportion of Subjects with Serious Infusion-Related Reactions including Hypersensitivity by Number of Risk Factors

No data to report

Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.43
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Number of Risk Factors

Number of risk factors: <=1

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	306	290
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 23.43
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Number of Risk Factors

Number of risk factors: 2

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	151	176
Any event	0	1 (0.6%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Table 23.43
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Number of Risk Factors

Number of risk factors: >=3

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	69	57
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Table 23.44
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	306	290
Any event	1 (0.3%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.44
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	151	176
Any event	2 (1.3%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.44
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	69	57
Any event	1 (1.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	306	290
Any event	17 (5.6%)	2 (0.7%)
Odds Ratio		0.12
95% CI		(0.01, 0.51)
Relative Risk		0.12
95% CI		(0.03, 0.53)
Risk Difference (%)		-4.87
95% CI		(-7.60, -2.13)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	10 (3.3%)	1 (0.3%)
Odds Ratio		0.10
95% CI		(0.00, 0.73)
Relative Risk		0.11
95% CI		(0.01, 0.82)
Risk Difference (%)		-2.92
95% CI		(-5.03, -0.82)
p-value [1]		0.011

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	9 (2.9%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	151	176
Any event	7 (4.6%)	4 (2.3%)
Odds Ratio		0.48
95% CI		(0.14, 1.67)
Relative Risk		0.49
95% CI		(0.15, 1.64)
Risk Difference (%)		-2.36
95% CI		(-6.37, 1.65)
p-value [1]		0.357

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	7 (4.6%)	2 (1.1%)
Odds Ratio		0.24
95% CI		(0.02, 1.27)
Relative Risk		0.25
95% CI		(0.05, 1.16)
Risk Difference (%)		-3.50
95% CI		(-7.20, 0.20)
p-value [1]		0.086

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	5 (3.3%)	1 (0.6%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	69	57
Any event	5 (7.2%)	5 (8.8%)
Odds Ratio		1.23
95% CI		(0.34, 4.48)
Relative Risk		1.21
95% CI		(0.37, 3.97)
Risk Difference (%)		1.53
95% CI		(-8.03, 11.08)
p-value [1]		0.754

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	5 (7.2%)	2 (3.5%)
Odds Ratio		0.47
95% CI		(0.09, 2.49)
Relative Risk		0.48
95% CI		(0.10, 2.40)
Risk Difference (%)		-3.74
95% CI		(-11.50, 4.02)
p-value [1]		0.455

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	4 (5.8%)	2 (3.5%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.46
Summary and Analysis of Proportion of Subjects with Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	231	233
Any event	49 (21.2%)	58 (24.9%)
Odds Ratio		1.23
95% CI		(0.80, 1.90)
Relative Risk		1.17
95% CI		(0.84, 1.64)
Risk Difference (%)		3.68
95% CI		(-3.98, 11.34)
p-value [1]		0.379

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.46
Summary and Analysis of Proportion of Subjects with Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	16 (6.9%)	9 (3.9%)
Odds Ratio		0.54
95% CI		(0.23, 1.25)
Relative Risk		0.56
95% CI		(0.25, 1.24)
Risk Difference (%)		-3.06
95% CI		(-7.17, 1.04)
p-value [1]		0.156

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.46
Summary and Analysis of Proportion of Subjects with Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	8 (3.5%)	2 (0.9%)
Odds Ratio		0.24
95% CI		(0.02, 1.23)
Relative Risk		0.25
95% CI		(0.05, 1.15)
Risk Difference (%)		-2.60
95% CI		(-5.24, 0.03)
p-value [1]		0.062

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.46
Summary and Analysis of Proportion of Subjects with Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	204	213
Any event	50 (24.5%)	39 (18.3%)
Odds Ratio		0.69
95% CI		(0.43, 1.11)
Relative Risk		0.75
95% CI		(0.51, 1.08)
Risk Difference (%)		-6.20
95% CI		(-14.06, 1.66)
p-value [1]		0.151

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.46
Summary and Analysis of Proportion of Subjects with Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	17 (8.3%)	4 (1.9%)
Odds Ratio		0.21
95% CI		(0.05, 0.66)
Relative Risk		0.23
95% CI		(0.08, 0.66)
Risk Difference (%)		-6.46
95% CI		(-10.66, -2.25)
p-value [1]		0.003

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.46
Summary and Analysis of Proportion of Subjects with Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	10 (4.9%)	2 (0.9%)
Odds Ratio		0.18
95% CI		(0.02, 0.88)
Relative Risk		0.19
95% CI		(0.04, 0.86)
Risk Difference (%)		-3.96
95% CI		(-7.20, -0.73)
p-value [1]		0.018

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.47
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	231	233
Any event	11 (4.8%)	5 (2.1%)
Odds Ratio		0.44
95% CI		(0.15, 1.28)
Relative Risk		0.45
95% CI		(0.16, 1.28)
Risk Difference (%)		-2.62
95% CI		(-5.93, 0.70)
p-value [1]		0.135

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.47
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	8 (3.5%)	3 (1.3%)
Odds Ratio		0.36
95% CI		(0.06, 1.54)
Relative Risk		0.37
95% CI		(0.10, 1.38)
Risk Difference (%)		-2.18
95% CI		(-4.94, 0.59)
p-value [1]		0.140

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.47
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	7 (3.0%)	2 (0.9%)
Odds Ratio		0.28
95% CI		(0.03, 1.48)
Relative Risk		0.28
95% CI		(0.06, 1.35)
Risk Difference (%)		-2.17
95% CI		(-4.68, 0.34)
p-value [1]		0.105

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.47
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	204	213
Any event	12 (5.9%)	5 (2.3%)
Odds Ratio		0.38
95% CI		(0.13, 1.11)
Relative Risk		0.40
95% CI		(0.14, 1.11)
Risk Difference (%)		-3.53
95% CI		(-7.35, 0.28)
p-value [1]		0.084

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.47
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	10 (4.9%)	2 (0.9%)
Odds Ratio		0.18
95% CI		(0.02, 0.88)
Relative Risk		0.19
95% CI		(0.04, 0.86)
Risk Difference (%)		-3.96
95% CI		(-7.20, -0.73)
p-value [1]		0.018

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.47
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	9 (4.4%)	1 (0.5%)
Odds Ratio		0.10
95% CI		(0.00, 0.75)
Relative Risk		0.11
95% CI		(0.01, 0.83)
Risk Difference (%)		-3.94
95% CI		(-6.91, -0.98)
p-value [1]		0.009

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.48
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	231	233
Any event	3 (1.3%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.48
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	204	213
Any event	1 (0.5%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.49
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	231	233
Any event	2 (0.9%)	2 (0.9%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.49
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	204	213
Any event	2 (1.0%)	4 (1.9%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.50
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	231	233
Any event	0	1 (0.4%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 23.50
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	204	213
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Table 23.51
Summary and Analysis of Proportion of Subjects with Serious Infusion-Related Reactions including Hypersensitivity by Patient Reported Symptom Severity

No data to report

Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.52
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	231	233
Any event	0	1 (0.4%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Table 23.52
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	204	213
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Table 23.53
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	231	233
Any event	2 (0.9%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.53
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	204	213
Any event	1 (0.5%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.54
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	231	233
Any event	9 (3.9%)	5 (2.1%)
Odds Ratio		0.54
95% CI		(0.18, 1.64)
Relative Risk		0.55
95% CI		(0.19, 1.62)
Risk Difference (%)		-1.75
95% CI		(-4.86, 1.36)
p-value [1]		0.293

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.54
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	6 (2.6%)	3 (1.3%)
Odds Ratio		0.49
95% CI		(0.08, 2.33)
Relative Risk		0.50
95% CI		(0.13, 1.96)
Risk Difference (%)		-1.31
95% CI		(-3.82, 1.20)
p-value [1]		0.337

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.54
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	6 (2.6%)	2 (0.9%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.54
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	204	213
Any event	11 (5.4%)	5 (2.3%)
Odds Ratio		0.42
95% CI		(0.14, 1.24)
Relative Risk		0.44
95% CI		(0.15, 1.23)
Risk Difference (%)		-3.04
95% CI		(-6.75, 0.66)
p-value [1]		0.129

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.54
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	9 (4.4%)	2 (0.9%)
Odds Ratio		0.21
95% CI		(0.02, 1.01)
Relative Risk		0.21
95% CI		(0.05, 0.97)
Risk Difference (%)		-3.47
95% CI		(-6.57, -0.37)
p-value [1]		0.033

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.54
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	8 (3.9%)	1 (0.5%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	15	13
Any event	5 (33.3%)	4 (30.8%)
Odds Ratio		0.89
95% CI		(0.18, 4.37)
Relative Risk		0.92
95% CI		(0.31, 2.73)
Risk Difference (%)		-2.56
95% CI		(-37.18, 32.06)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	3 (20.0%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-20.00
95% CI		(-40.24, 0.24)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (13.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-13.33
95% CI		(-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	499	499
Any event	111 (22.2%)	104 (20.8%)
Odds Ratio		0.92
95% CI		(0.68, 1.24)
Relative Risk		0.94
95% CI		(0.74, 1.19)
Risk Difference (%)		-1.40
95% CI		(-6.50, 3.70)
p-value [1]		0.644

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	35 (7.0%)	16 (3.2%)
Odds Ratio		0.44
95% CI		(0.24, 0.80)
Relative Risk		0.46
95% CI		(0.26, 0.82)
Risk Difference (%)		-3.81
95% CI		(-6.53, -1.09)
p-value [1]		0.009

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	17 (3.4%)	5 (1.0%)
Odds Ratio		0.29
95% CI		(0.08, 0.82)
Relative Risk		0.29
95% CI		(0.11, 0.79)
Risk Difference (%)		-2.40
95% CI		(-4.22, -0.59)
p-value [1]		0.016

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	12	11
Any event	7 (58.3%)	6 (54.5%)
Odds Ratio		0.86
95% CI		(0.16, 4.47)
Relative Risk		0.94
95% CI		(0.45, 1.92)
Risk Difference (%)		-3.79
95% CI		(-44.33, 36.76)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	5 (41.7%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-41.67
95% CI		(-69.56, -13.77)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	3 (25.0%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-25.00
95% CI		(-49.50, -0.50)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	15	13
Any event	2 (13.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-13.33
95% CI		(-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	2 (13.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-13.33
95% CI		(-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (13.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-13.33
95% CI		(-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	499	499
Any event	25 (5.0%)	11 (2.2%)
Odds Ratio		0.43
95% CI		(0.21, 0.88)
Relative Risk		0.44
95% CI		(0.22, 0.88)
Risk Difference (%)		-2.81
95% CI		(-5.11, -0.50)
p-value [1]		0.026

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	19 (3.8%)	5 (1.0%)
Odds Ratio		0.26
95% CI		(0.07, 0.72)
Relative Risk		0.26
95% CI		(0.10, 0.70)
Risk Difference (%)		-2.81
95% CI		(-4.70, -0.91)
p-value [1]		0.006

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	15 (3.0%)	3 (0.6%)
Odds Ratio		0.20
95% CI		(0.04, 0.70)
Relative Risk		0.20
95% CI		(0.06, 0.69)
Risk Difference (%)		-2.40
95% CI		(-4.05, -0.76)
p-value [1]		0.007

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	12	11
Any event	5 (41.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-41.67 (-69.56, -13.77)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	4 (33.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-33.33
95% CI		(-60.01, -6.66)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	3 (25.0%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-25.00
95% CI		(-49.50, -0.50)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.57
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	15	13
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.57
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	499	499
Any event	4 (0.8%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.57
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	12	11
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.58
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Region

Region: Europe

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	15	13
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.58
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Region

Region: North America

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	499	499
Any event	5 (1.0%)	6 (1.2%)
Odds Ratio		1.20
95% CI		(0.30, 5.01)
Relative Risk		1.20
95% CI		(0.37, 3.91)
Risk Difference (%)		0.20
95% CI		(-1.10, 1.50)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.58
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Region

Region: South America

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	12	11
Any event	1 (8.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-8.33
95% CI		(-23.97, 7.30)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

Table 23.59
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Region

Region: Europe

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	15	13
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 23.59
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Region

Region: North America

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	499	499
Any event	0	1 (0.2%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 23.59
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Region

Region: South America

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	12	11
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Protocol: 214367
Population: Safety Data as of 27APR2021

Table 23.60
Summary and Analysis of Proportion of Subjects with Serious Infusion-Related Reactions including Hypersensitivity by Region

No data to report

Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.61
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Region

Region: Europe

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	15	13
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 23.61
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Region

Region: North America

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	499	499
Any event	0	1 (0.2%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 23.61
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Region

Region: South America

Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	12	11
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Table 23.62
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	15	13
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.62
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	499	499
Any event	3 (0.6%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.62
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	12	11
Any event	1 (8.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	15	13
Any event	2 (13.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-13.33
95% CI		(-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	2 (13.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-13.33
95% CI		(-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (13.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-13.33
95% CI		(-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	499	499
Any event	22 (4.4%)	11 (2.2%)
Odds Ratio		0.49
95% CI		(0.23, 1.02)
Relative Risk		0.50
95% CI		(0.25, 1.02)
Risk Difference (%)		-2.20
95% CI		(-4.42, 0.01)
p-value [1]		0.075

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	16 (3.2%)	5 (1.0%)
Odds Ratio		0.31
95% CI		(0.09, 0.88)
Relative Risk		0.31
95% CI		(0.12, 0.85)
Risk Difference (%)		-2.20
95% CI		(-3.98, -0.43)
p-value [1]		0.025

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	13 (2.6%)	3 (0.6%)
Odds Ratio		0.23
95% CI		(0.04, 0.83)
Relative Risk		0.23
95% CI		(0.07, 0.80)
Risk Difference (%)		-2.00
95% CI		(-3.56, -0.45)
p-value [1]		0.020

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	12	11
Any event	5 (41.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-41.67 (-69.56, -13.77)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	4 (33.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-33.33
95% CI		(-60.01, -6.66)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	3 (25.0%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-25.00
95% CI		(-49.50, -0.50)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.74
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	470	468
Any event	34 (7.2%)	11 (2.4%)
Odds Ratio		0.31
95% CI		(0.15, 0.62)
Relative Risk		0.32
95% CI		(0.17, 0.63)
Risk Difference (%)		-4.88
95% CI		(-7.60, -2.17)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.74
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	21 (4.5%)	1 (0.2%)
Odds Ratio		0.05
95% CI		(0.00, 0.29)
Relative Risk		0.05
95% CI		(0.01, 0.35)
Risk Difference (%)		-4.25
95% CI		(-6.17, -2.34)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.74
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	18 (3.8%)	1 (0.2%)
Odds Ratio		0.05
95% CI		(0.00, 0.34)
Relative Risk		0.06
95% CI		(0.01, 0.42)
Risk Difference (%)		-3.62
95% CI		(-5.40, -1.83)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.74
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	56	55
Any event	5 (8.9%)	4 (7.3%)
Odds Ratio		0.80
95% CI		(0.20, 3.15)
Relative Risk		0.81
95% CI		(0.23, 2.87)
Risk Difference (%)		-1.66
95% CI		(-11.80, 8.49)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.74
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	4 (7.1%)	3 (5.5%)
Odds Ratio		0.75
95% CI		(0.16, 3.52)
Relative Risk		0.76
95% CI		(0.18, 3.26)
Risk Difference (%)		-1.69
95% CI		(-10.72, 7.34)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.74
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	3 (5.4%)	2 (3.6%)
Odds Ratio		0.67
95% CI		(0.11, 4.15)
Relative Risk		0.68
95% CI		(0.12, 3.91)
Risk Difference (%)		-1.72
95% CI		(-9.42, 5.98)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	96	98
Any event	3 (3.1%)	4 (4.1%)
Odds Ratio		1.32
95% CI		(0.29, 6.06)
Relative Risk		1.31
95% CI		(0.30, 5.68)
Risk Difference (%)		0.96
95% CI		(-4.28, 6.20)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	0	2 (2.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		2.04
95% CI		(-0.76, 4.84)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	0	1 (1.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		1.02
95% CI		(-0.97, 3.01)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	84	72
Any event	3 (3.6%)	2 (2.8%)
Odds Ratio		0.77
95% CI		(0.13, 4.75)
Relative Risk		0.78
95% CI		(0.13, 4.53)
Risk Difference (%)		-0.79
95% CI		(-6.29, 4.70)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	58	64
Any event	6 (10.3%)	1 (1.6%)
Odds Ratio		0.14
95% CI		(0.00, 1.21)
Relative Risk		0.15
95% CI		(0.02, 1.22)
Risk Difference (%)		-8.78
95% CI		(-17.19, -0.38)
p-value [1]		0.052

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	5 (8.6%)	1 (1.6%)
Odds Ratio		0.17
95% CI		(0.00, 1.59)
Relative Risk		0.18
95% CI		(0.02, 1.51)
Risk Difference (%)		-7.06
95% CI		(-14.89, 0.78)
p-value [1]		0.101

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	4 (6.9%)	1 (1.6%)
Odds Ratio		0.21
95% CI		(0.00, 2.28)
Relative Risk		0.23
95% CI		(0.03, 1.97)
Risk Difference (%)		-5.33
95% CI		(-12.53, 1.86)
p-value [1]		0.190

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	60	73
Any event	3 (5.0%)	2 (2.7%)
Odds Ratio		0.54
95% CI		(0.09, 3.31)
Relative Risk		0.55
95% CI		(0.09, 3.17)
Risk Difference (%)		-2.26
95% CI		(-8.93, 4.41)
p-value [1]		0.657

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	2 (3.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.33
95% CI		(-7.88, 1.21)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (3.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.33
95% CI		(-7.88, 1.21)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	181	160
Any event	20 (11.0%)	4 (2.5%)
Odds Ratio		0.21
95% CI		(0.07, 0.62)
Relative Risk		0.23
95% CI		(0.08, 0.65)
Risk Difference (%)		-8.55
95% CI		(-13.72, -3.38)
p-value [1]		0.002

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	15 (8.3%)	1 (0.6%)
Odds Ratio		0.07
95% CI		(0.00, 0.46)
Relative Risk		0.08
95% CI		(0.01, 0.56)
Risk Difference (%)		-7.66
95% CI		(-11.86, -3.46)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	12 (6.6%)	1 (0.6%)
Odds Ratio		0.09
95% CI		(0.00, 0.61)
Relative Risk		0.09
95% CI		(0.01, 0.72)
Risk Difference (%)		-6.00
95% CI		(-9.83, -2.18)
p-value [1]		0.004

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.76
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	255	228
Any event	23 (9.0%)	6 (2.6%)
Odds Ratio		0.27
95% CI		(0.11, 0.68)
Relative Risk		0.29
95% CI		(0.12, 0.70)
Risk Difference (%)		-6.39
95% CI		(-10.47, -2.30)
p-value [1]		0.003

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.76
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	15 (5.9%)	2 (0.9%)
Odds Ratio		0.14
95% CI		(0.02, 0.62)
Relative Risk		0.15
95% CI		(0.03, 0.65)
Risk Difference (%)		-5.01
95% CI		(-8.14, -1.87)
p-value [1]		0.003

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.76
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	12 (4.7%)	2 (0.9%)
Odds Ratio		0.18
95% CI		(0.02, 0.82)
Relative Risk		0.19
95% CI		(0.04, 0.82)
Risk Difference (%)		-3.83
95% CI		(-6.70, -0.96)
p-value [1]		0.014

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.76
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	271	295
Any event	16 (5.9%)	9 (3.1%)
Odds Ratio		0.50
95% CI		(0.22, 1.15)
Relative Risk		0.52
95% CI		(0.23, 1.15)
Risk Difference (%)		-2.85
95% CI		(-6.28, 0.57)
p-value [1]		0.106

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.76
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	10 (3.7%)	2 (0.7%)
Odds Ratio		0.18
95% CI		(0.02, 0.85)
Relative Risk		0.18
95% CI		(0.04, 0.83)
Risk Difference (%)		-3.01
95% CI		(-5.44, -0.58)
p-value [1]		0.017

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.76
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	9 (3.3%)	1 (0.3%)
Odds Ratio		0.10
95% CI		(0.00, 0.73)
Relative Risk		0.10
95% CI		(0.01, 0.80)
Risk Difference (%)		-2.98
95% CI		(-5.22, -0.75)
p-value [1]		0.008

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	306	290
Any event	20 (6.5%)	5 (1.7%)
Odds Ratio		0.25
95% CI		(0.07, 0.70)
Relative Risk		0.26
95% CI		(0.10, 0.69)
Risk Difference (%)		-4.81
95% CI		(-7.96, -1.66)
p-value [1]		0.004

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	11 (3.6%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.59
95% CI		(-5.68, -1.51)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	9 (2.9%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	151	176
Any event	9 (6.0%)	5 (2.8%)
Odds Ratio		0.46
95% CI		(0.15, 1.41)
Relative Risk		0.48
95% CI		(0.16, 1.39)
Risk Difference (%)		-3.12
95% CI		(-7.62, 1.38)
p-value [1]		0.182

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	7 (4.6%)	2 (1.1%)
Odds Ratio		0.24
95% CI		(0.02, 1.27)
Relative Risk		0.25
95% CI		(0.05, 1.16)
Risk Difference (%)		-3.50
95% CI		(-7.20, 0.20)
p-value [1]		0.086

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	7 (4.6%)	1 (0.6%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	69	57
Any event	10 (14.5%)	5 (8.8%)
Odds Ratio		0.57
95% CI		(0.18, 1.77)
Relative Risk		0.61
95% CI		(0.22, 1.67)
Risk Difference (%)		-5.72
95% CI		(-16.81, 5.37)
p-value [1]		0.412

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	7 (10.1%)	2 (3.5%)
Odds Ratio		0.32
95% CI		(0.06, 1.62)
Relative Risk		0.35
95% CI		(0.07, 1.60)
Risk Difference (%)		-6.64
95% CI		(-15.21, 1.94)
p-value [1]		0.182

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	5 (7.2%)	2 (3.5%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.78
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	231	233
Any event	15 (6.5%)	3 (1.3%)
Odds Ratio		0.19
95% CI		(0.03, 0.68)
Relative Risk		0.20
95% CI		(0.06, 0.68)
Risk Difference (%)		-5.21
95% CI		(-8.70, -1.71)
p-value [1]		0.004

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.78
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	9 (3.9%)	2 (0.9%)
Odds Ratio		0.21
95% CI		(0.02, 1.05)
Relative Risk		0.22
95% CI		(0.05, 1.01)
Risk Difference (%)		-3.04
95% CI		(-5.80, -0.28)
p-value [1]		0.036

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.78
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	8 (3.5%)	2 (0.9%)
Odds Ratio		0.24
95% CI		(0.02, 1.23)
Relative Risk		0.25
95% CI		(0.05, 1.15)
Risk Difference (%)		-2.60
95% CI		(-5.24, 0.03)
p-value [1]		0.062

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.78
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	204	213
Any event	18 (8.8%)	10 (4.7%)
Odds Ratio		0.51
95% CI		(0.23, 1.13)
Relative Risk		0.53
95% CI		(0.25, 1.13)
Risk Difference (%)		-4.13
95% CI		(-8.95, 0.69)
p-value [1]		0.117

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.78
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	11 (5.4%)	2 (0.9%)
Odds Ratio		0.17
95% CI		(0.02, 0.78)
Relative Risk		0.17
95% CI		(0.04, 0.78)
Risk Difference (%)		-4.45
95% CI		(-7.81, -1.09)
p-value [1]		0.010

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.78
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	10 (4.9%)	1 (0.5%)
Odds Ratio		0.09
95% CI		(0.00, 0.66)
Relative Risk		0.10
95% CI		(0.01, 0.74)
Risk Difference (%)		-4.43
95% CI		(-7.53, -1.33)
p-value [1]		0.005

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	15	13
Any event	2 (13.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-13.33
95% CI		(-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	2 (13.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-13.33
95% CI		(-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	1 (6.7%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-6.67
95% CI		(-19.29, 5.96)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	499	499
Any event	33 (6.6%)	14 (2.8%)
Odds Ratio		0.41
95% CI		(0.22, 0.77)
Relative Risk		0.42
95% CI		(0.23, 0.78)
Risk Difference (%)		-3.81
95% CI		(-6.43, -1.19)
p-value [1]		0.007

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	19 (3.8%)	4 (0.8%)
Odds Ratio		0.20
95% CI		(0.05, 0.62)
Relative Risk		0.21
95% CI		(0.07, 0.61)
Risk Difference (%)		-3.01
95% CI		(-4.86, -1.15)
p-value [1]		0.002

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	17 (3.4%)	3 (0.6%)
Odds Ratio		0.17
95% CI		(0.03, 0.60)
Relative Risk		0.18
95% CI		(0.05, 0.60)
Risk Difference (%)		-2.81
95% CI		(-4.54, -1.08)
p-value [1]		0.002

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	12	11
Any event	4 (33.3%)	1 (9.1%)
Odds Ratio		0.20
95% CI		(0.02, 2.16)
Relative Risk		0.27
95% CI		(0.04, 2.08)
Risk Difference (%)		-24.24
95% CI		(-55.87, 7.38)
p-value [1]		0.317

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	4 (33.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-33.33
95% CI		(-60.01, -6.66)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 23.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
COVID-19 pneumonia	3 (25.0%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-25.00
95% CI		(-49.50, -0.50)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 23.86
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	470	468
Any event	89 (18.9%)	95 (20.3%)
Odds Ratio		1.09
95% CI		(0.79, 1.51)
Relative Risk		1.07
95% CI		(0.83, 1.39)
Risk Difference (%)		1.36
95% CI		(-3.72, 6.44)
p-value [1]		0.622

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.86
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	19 (4.0%)	9 (1.9%)
Odds Ratio		0.47
95% CI		(0.18, 1.09)
Relative Risk		0.48
95% CI		(0.22, 1.04)
Risk Difference (%)		-2.12
95% CI		(-4.29, 0.05)
p-value [1]		0.082

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.86
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	56	55
Any event	12 (21.4%)	15 (27.3%)
Odds Ratio		1.38
95% CI		(0.58, 3.29)
Relative Risk		1.27
95% CI		(0.66, 2.47)
Risk Difference (%)		5.84
95% CI		(-10.09, 21.78)
p-value [1]		0.513

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.86
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	7 (12.5%)	3 (5.5%)
Odds Ratio		0.40
95% CI		(0.10, 1.65)
Relative Risk		0.44
95% CI		(0.12, 1.60)
Risk Difference (%)		-7.05
95% CI		(-17.58, 3.49)
p-value [1]		0.321

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Protocol: 214367
Population: Safety Data as of 27APR2021

Table 23.87
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	470	468
Any event	18 (3.8%)	9 (1.9%)
Odds Ratio		0.49
95% CI		(0.19, 1.17)
Relative Risk		0.50
95% CI		(0.23, 1.11)
Risk Difference (%)		-1.91
95% CI		(-4.04, 0.23)
p-value [1]		0.117

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.87
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	56	55
Any event	3 (5.4%)	4 (7.3%)
Odds Ratio		1.39
95% CI		(0.30, 6.50)
Relative Risk		1.36
95% CI		(0.32, 5.79)
Risk Difference (%)		1.92
95% CI		(-7.13, 10.96)
p-value [1]		0.716

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.88
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	470	468
Any event	9 (1.9%)	6 (1.3%)
Odds Ratio		0.67
95% CI		(0.19, 2.11)
Relative Risk		0.67
95% CI		(0.24, 1.87)
Risk Difference (%)		-0.63
95% CI		(-2.24, 0.97)
p-value [1]		0.604

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Protocol: 214367
Population: Safety Data as of 27APR2021

Table 23.88
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	56	55
Any event	6 (10.7%)	3 (5.5%)
Odds Ratio		0.48
95% CI		(0.11, 2.03)
Relative Risk		0.51
95% CI		(0.13, 1.93)
Risk Difference (%)		-5.26
95% CI		(-15.34, 4.82)
p-value [1]		0.489

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.89
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	470	468
Any event	2 (0.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.89
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	56	55
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.90
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	470	468
Any event	8 (1.7%)	6 (1.3%)
Odds Ratio		0.75
95% CI		(0.21, 2.49)
Relative Risk		0.75
95% CI		(0.26, 2.15)
Risk Difference (%)		-0.42
95% CI		(-1.97, 1.13)
p-value [1]		0.789

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.90
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	56	55
Any event	6 (10.7%)	3 (5.5%)
Odds Ratio		0.48
95% CI		(0.11, 2.03)
Relative Risk		0.51
95% CI		(0.13, 1.93)
Risk Difference (%)		-5.26
95% CI		(-15.34, 4.82)
p-value [1]		0.489

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	96	98
Any event	17 (17.7%)	21 (21.4%)
Odds Ratio		1.27
95% CI		(0.62, 2.58)
Relative Risk		1.21
95% CI		(0.68, 2.15)
Risk Difference (%)		3.72
95% CI		(-7.43, 14.87)
p-value [1]		0.589

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	2 (2.1%)	4 (4.1%)
Odds Ratio		2.00
95% CI		(0.36, 11.18)
Relative Risk		1.96
95% CI		(0.37, 10.45)
Risk Difference (%)		2.00
95% CI		(-2.85, 6.85)
p-value [1]		0.683

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	84	72
Any event	16 (19.0%)	16 (22.2%)
Odds Ratio		1.21
95% CI		(0.56, 2.64)
Relative Risk		1.17
95% CI		(0.63, 2.16)
Risk Difference (%)		3.17
95% CI		(-9.58, 15.93)
p-value [1]		0.693

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	7 (8.3%)	3 (4.2%)
Odds Ratio		0.48
95% CI		(0.12, 1.92)
Relative Risk		0.50
95% CI		(0.13, 1.86)
Risk Difference (%)		-4.17
95% CI		(-11.67, 3.33)
p-value [1]		0.343

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	58	64
Any event	14 (24.1%)	15 (23.4%)
Odds Ratio		0.96
95% CI		(0.42, 2.22)
Relative Risk		0.97
95% CI		(0.51, 1.83)
Risk Difference (%)		-0.70
95% CI		(-15.83, 14.43)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	3 (5.2%)	1 (1.6%)
Odds Ratio		0.29
95% CI		(0.01, 3.78)
Relative Risk		0.30
95% CI		(0.03, 2.82)
Risk Difference (%)		-3.61
95% CI		(-10.07, 2.85)
p-value [1]		0.345

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	60	73
Any event	14 (23.3%)	13 (17.8%)
Odds Ratio		0.71
95% CI		(0.31, 1.66)
Relative Risk		0.76
95% CI		(0.39, 1.50)
Risk Difference (%)		-5.53
95% CI		(-19.37, 8.32)
p-value [1]		0.517

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	4 (6.7%)	1 (1.4%)
Odds Ratio		0.19
95% CI		(0.00, 2.06)
Relative Risk		0.21
95% CI		(0.02, 1.79)
Risk Difference (%)		-5.30
95% CI		(-12.15, 1.55)
p-value [1]		0.174

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	181	160
Any event	33 (18.2%)	29 (18.1%)
Odds Ratio		0.99
95% CI		(0.57, 1.72)
Relative Risk		0.99
95% CI		(0.63, 1.56)
Risk Difference (%)		-0.11
95% CI		(-8.31, 8.09)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	10 (5.5%)	2 (1.3%)
Odds Ratio		0.22
95% CI		(0.02, 1.04)
Relative Risk		0.23
95% CI		(0.05, 1.02)
Risk Difference (%)		-4.27
95% CI		(-8.02, -0.53)
p-value [1]		0.040

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.92
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	96	98
Any event	3 (3.1%)	4 (4.1%)
Odds Ratio		1.32
95% CI		(0.29, 6.06)
Relative Risk		1.31
95% CI		(0.30, 5.68)
Risk Difference (%)		0.96
95% CI		(-4.28, 6.20)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.92
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	84	72
Any event	3 (3.6%)	1 (1.4%)
Odds Ratio		0.38
95% CI		(0.01, 4.88)
Relative Risk		0.39
95% CI		(0.04, 3.66)
Risk Difference (%)		-2.18
95% CI		(-6.98, 2.62)
p-value [1]		0.625

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.92
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	58	64
Any event	2 (3.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-3.45 (-8.14, 1.25)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.92
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	60	73
Any event	1 (1.7%)	2 (2.7%)
Odds Ratio		1.66
95% CI		(0.08, 99.69)
Relative Risk		1.64
95% CI		(0.15, 17.69)
Risk Difference (%)		1.07
95% CI		(-3.88, 6.02)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.92
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	181	160
Any event	10 (5.5%)	4 (2.5%)
Odds Ratio		0.44
95% CI		(0.13, 1.43)
Relative Risk		0.45
95% CI		(0.14, 1.41)
Risk Difference (%)		-3.02
95% CI		(-7.14, 1.09)
p-value [1]		0.182

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.93
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	96	98
Any event	0	2 (2.0%)
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		2.04 (-0.76, 4.84)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.93
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	84	72
Any event	3 (3.6%)	1 (1.4%)
Odds Ratio		0.38
95% CI		(0.01, 4.88)
Relative Risk		0.39
95% CI		(0.04, 3.66)
Risk Difference (%)		-2.18
95% CI		(-6.98, 2.62)
p-value [1]		0.625

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.93
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	58	64
Any event	2 (3.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-3.45 (-8.14, 1.25)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.93
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	60	73
Any event	1 (1.7%)	1 (1.4%)
Odds Ratio		0.82
95% CI		(0.01, 65.40)
Relative Risk		0.82
95% CI		(0.05, 12.87)
Risk Difference (%)		-0.30
95% CI		(-4.49, 3.90)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.93
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	181	160
Any event	9 (5.0%)	3 (1.9%)
Odds Ratio		0.37
95% CI		(0.06, 1.50)
Relative Risk		0.38
95% CI		(0.10, 1.37)
Risk Difference (%)		-3.10
95% CI		(-6.90, 0.70)
p-value [1]		0.148

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.94
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	96	98
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.94
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	84	72
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.94
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	58	64
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.94
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	60	73
Any event	1 (1.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.94
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	181	160
Any event	1 (0.6%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.95
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	96	98
Any event	0	2 (2.0%)
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		2.04 (-0.76, 4.84)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.95
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	84	72
Any event	3 (3.6%)	1 (1.4%)
Odds Ratio		0.38
95% CI		(0.01, 4.88)
Relative Risk		0.39
95% CI		(0.04, 3.66)
Risk Difference (%)		-2.18
95% CI		(-6.98, 2.62)
p-value [1]		0.625

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.95
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	58	64
Any event	2 (3.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-3.45 (-8.14, 1.25)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.95
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	60	73
Any event	1 (1.7%)	1 (1.4%)
Odds Ratio		0.82
95% CI		(0.01, 65.40)
Relative Risk		0.82
95% CI		(0.05, 12.87)
Risk Difference (%)		-0.30
95% CI		(-4.49, 3.90)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.95
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	181	160
Any event	8 (4.4%)	3 (1.9%)
Odds Ratio		0.41
95% CI		(0.07, 1.76)
Relative Risk		0.42
95% CI		(0.11, 1.57)
Risk Difference (%)		-2.54
95% CI		(-6.20, 1.11)
p-value [1]		0.229

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.96
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	255	228
Any event	53 (20.8%)	36 (15.8%)
Odds Ratio		0.71
95% CI		(0.45, 1.14)
Relative Risk		0.76
95% CI		(0.52, 1.12)
Risk Difference (%)		-4.99
95% CI		(-11.87, 1.88)
p-value [1]		0.161

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.96
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	10 (3.9%)	8 (3.5%)
Odds Ratio		0.89
95% CI		(0.35, 2.30)
Relative Risk		0.89
95% CI		(0.36, 2.23)
Risk Difference (%)		-0.41
95% CI		(-3.79, 2.96)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.96
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	271	295
Any event	48 (17.7%)	74 (25.1%)
Odds Ratio		1.56
95% CI		(1.03, 2.34)
Relative Risk		1.42
95% CI		(1.02, 1.96)
Risk Difference (%)		7.37
95% CI		(0.65, 14.09)
p-value [1]		0.040

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.96
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	16 (5.9%)	4 (1.4%)
Odds Ratio		0.22
95% CI		(0.05, 0.69)
Relative Risk		0.23
95% CI		(0.08, 0.68)
Risk Difference (%)		-4.55
95% CI		(-7.65, -1.45)
p-value [1]		0.005

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.97
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	255	228
Any event	14 (5.5%)	5 (2.2%)
Odds Ratio		0.39
95% CI		(0.14, 1.09)
Relative Risk		0.40
95% CI		(0.15, 1.09)
Risk Difference (%)		-3.30
95% CI		(-6.68, 0.08)
p-value [1]		0.098

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.97
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	271	295
Any event	7 (2.6%)	8 (2.7%)
Odds Ratio		1.05
95% CI		(0.38, 2.94)
Relative Risk		1.05
95% CI		(0.39, 2.86)
Risk Difference (%)		0.13
95% CI		(-2.52, 2.78)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.98
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	255	228
Any event	10 (3.9%)	5 (2.2%)
Odds Ratio		0.55
95% CI		(0.18, 1.63)
Relative Risk		0.56
95% CI		(0.19, 1.61)
Risk Difference (%)		-1.73
95% CI		(-4.78, 1.32)
p-value [1]		0.306

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.98
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	271	295
Any event	5 (1.8%)	4 (1.4%)
Odds Ratio		0.73
95% CI		(0.14, 3.44)
Relative Risk		0.73
95% CI		(0.20, 2.71)
Risk Difference (%)		-0.49
95% CI		(-2.56, 1.59)
p-value [1]		0.743

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.99
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	255	228
Any event	1 (0.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.99
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	271	295
Any event	1 (0.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.100
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	255	228
Any event	9 (3.5%)	5 (2.2%)
Odds Ratio		0.61
95% CI		(0.20, 1.86)
Relative Risk		0.62
95% CI		(0.21, 1.83)
Risk Difference (%)		-1.34
95% CI		(-4.29, 1.62)
p-value [1]		0.428

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.100
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	271	295
Any event	5 (1.8%)	4 (1.4%)
Odds Ratio		0.73
95% CI		(0.14, 3.44)
Relative Risk		0.73
95% CI		(0.20, 2.71)
Risk Difference (%)		-0.49
95% CI		(-2.56, 1.59)
p-value [1]		0.743

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.101
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	306	290
Any event	56 (18.3%)	58 (20.0%)
Odds Ratio		1.12
95% CI		(0.74, 1.68)
Relative Risk		1.09
95% CI		(0.79, 1.52)
Risk Difference (%)		1.70
95% CI		(-4.62, 8.02)
p-value [1]		0.604

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.101
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	12 (3.9%)	3 (1.0%)
Odds Ratio		0.26
95% CI		(0.05, 0.96)
Relative Risk		0.26
95% CI		(0.08, 0.93)
Risk Difference (%)		-2.89
95% CI		(-5.35, -0.42)
p-value [1]		0.034

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.101
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	151	176
Any event	28 (18.5%)	39 (22.2%)
Odds Ratio		1.25
95% CI		(0.73, 2.15)
Relative Risk		1.20
95% CI		(0.77, 1.84)
Risk Difference (%)		3.62
95% CI		(-5.11, 12.34)
p-value [1]		0.492

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.101
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	6 (4.0%)	6 (3.4%)
Odds Ratio		0.85
95% CI		(0.27, 2.70)
Relative Risk		0.86
95% CI		(0.28, 2.60)
Risk Difference (%)		-0.56
95% CI		(-4.67, 3.55)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.



Table 23.101
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	69	57
Any event	17 (24.6%)	13 (22.8%)
Odds Ratio		0.90
95% CI		(0.40, 2.06)
Relative Risk		0.93
95% CI		(0.49, 1.74)
Risk Difference (%)		-1.83
95% CI		(-16.73, 13.07)
p-value [1]		0.837

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.101
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	8 (11.6%)	3 (5.3%)
Odds Ratio		0.42
95% CI		(0.11, 1.68)
Relative Risk		0.45
95% CI		(0.13, 1.63)
Risk Difference (%)		-6.33
95% CI		(-15.85, 3.19)
p-value [1]		0.342

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.



Table 23.102
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	306	290
Any event	11 (3.6%)	4 (1.4%)
Odds Ratio		0.38
95% CI		(0.09, 1.29)
Relative Risk		0.38
95% CI		(0.12, 1.19)
Risk Difference (%)		-2.22
95% CI		(-4.70, 0.26)
p-value [1]		0.116

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.102
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	151	176
Any event	3 (2.0%)	5 (2.8%)
Odds Ratio		1.44
95% CI		(0.28, 9.43)
Relative Risk		1.43
95% CI		(0.35, 5.88)
Risk Difference (%)		0.85
95% CI		(-2.46, 4.17)
p-value [1]		0.730

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.102
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	69	57
Any event	7 (10.1%)	4 (7.0%)
Odds Ratio		0.67
95% CI		(0.19, 2.41)
Relative Risk		0.69
95% CI		(0.21, 2.25)
Risk Difference (%)		-3.13
95% CI		(-12.86, 6.61)
p-value [1]		0.753

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.103
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	306	290
Any event	8 (2.6%)	2 (0.7%)
Odds Ratio		0.26
95% CI		(0.03, 1.31)
Relative Risk		0.26
95% CI		(0.06, 1.23)
Risk Difference (%)		-1.92
95% CI		(-3.95, 0.10)
p-value [1]		0.108

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.103
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	151	176
Any event	4 (2.6%)	4 (2.3%)
Odds Ratio		0.85
95% CI		(0.21, 3.48)
Relative Risk		0.86
95% CI		(0.22, 3.37)
Risk Difference (%)		-0.38
95% CI		(-3.75, 3.00)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.103
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	69	57
Any event	3 (4.3%)	3 (5.3%)
Odds Ratio		1.22
95% CI		(0.24, 6.30)
Relative Risk		1.21
95% CI		(0.25, 5.77)
Risk Difference (%)		0.92
95% CI		(-6.62, 8.45)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.104
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	306	290
Any event	1 (0.3%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.104
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	151	176
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.104
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	69	57
Any event	1 (1.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.105
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	306	290
Any event	8 (2.6%)	2 (0.7%)
Odds Ratio		0.26
95% CI		(0.03, 1.31)
Relative Risk		0.26
95% CI		(0.06, 1.23)
Risk Difference (%)		-1.92
95% CI		(-3.95, 0.10)
p-value [1]		0.108

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.105
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	151	176
Any event	4 (2.6%)	4 (2.3%)
Odds Ratio		0.85
95% CI		(0.21, 3.48)
Relative Risk		0.86
95% CI		(0.22, 3.37)
Risk Difference (%)		-0.38
95% CI		(-3.75, 3.00)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.105
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	69	57
Any event	2 (2.9%)	3 (5.3%)
Odds Ratio		1.86
95% CI		(0.30, 11.54)
Relative Risk		1.82
95% CI		(0.31, 10.50)
Risk Difference (%)		2.36
95% CI		(-4.65, 9.38)
p-value [1]		0.658

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.106
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	231	233
Any event	42 (18.2%)	57 (24.5%)
Odds Ratio		1.46
95% CI		(0.93, 2.28)
Relative Risk		1.35
95% CI		(0.94, 1.92)
Risk Difference (%)		6.28
95% CI		(-1.15, 13.71)
p-value [1]		0.113

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.106
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	11 (4.8%)	8 (3.4%)
Odds Ratio		0.71
95% CI		(0.28, 1.80)
Relative Risk		0.72
95% CI		(0.30, 1.76)
Risk Difference (%)		-1.33
95% CI		(-4.94, 2.28)
p-value [1]		0.493

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.106
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	204	213
Any event	37 (18.1%)	37 (17.4%)
Odds Ratio		0.95
95% CI		(0.57, 1.57)
Relative Risk		0.96
95% CI		(0.63, 1.45)
Risk Difference (%)		-0.77
95% CI		(-8.10, 6.57)
p-value [1]		0.898

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.



Table 23.106
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	8 (3.9%)	2 (0.9%)
Odds Ratio		0.23
95% CI		(0.02, 1.19)
Relative Risk		0.24
95% CI		(0.05, 1.11)
Risk Difference (%)		-2.98
95% CI		(-5.94, -0.02)
p-value [1]		0.058

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.107
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	231	233
Any event	9 (3.9%)	3 (1.3%)
Odds Ratio		0.32
95% CI		(0.06, 1.31)
Relative Risk		0.33
95% CI		(0.09, 1.21)
Risk Difference (%)		-2.61
95% CI		(-5.49, 0.28)
p-value [1]		0.087

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.107
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	204	213
Any event	8 (3.9%)	8 (3.8%)
Odds Ratio		0.96
95% CI		(0.35, 2.60)
Relative Risk		0.96
95% CI		(0.37, 2.50)
Risk Difference (%)		-0.17
95% CI		(-3.86, 3.52)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.108
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	231	233
Any event	6 (2.6%)	4 (1.7%)
Odds Ratio		0.66
95% CI		(0.13, 2.81)
Relative Risk		0.66
95% CI		(0.19, 2.31)
Risk Difference (%)		-0.88
95% CI		(-3.52, 1.76)
p-value [1]		0.543

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.108
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	204	213
Any event	3 (1.5%)	4 (1.9%)
Odds Ratio		1.28
95% CI		(0.21, 8.86)
Relative Risk		1.28
95% CI		(0.29, 5.64)
Risk Difference (%)		0.41
95% CI		(-2.05, 2.87)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.109
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	231	233
Any event	2 (0.9%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.109
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	204	213
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.110
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	231	233
Any event	5 (2.2%)	4 (1.7%)
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.110
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	204	213
Any event	3 (1.5%)	4 (1.9%)
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.111
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	15	13
Any event	4 (26.7%)	4 (30.8%)
Odds Ratio		1.22
95% CI		(0.24, 6.31)
Relative Risk		1.15
95% CI		(0.36, 3.72)
Risk Difference (%)		4.10
95% CI		(-29.52, 37.72)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.111
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	2 (13.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-13.33
95% CI		(-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.111
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	499	499
Any event	91 (18.2%)	101 (20.2%)
Odds Ratio		1.14
95% CI		(0.83, 1.56)
Relative Risk		1.11
95% CI		(0.86, 1.43)
Risk Difference (%)		2.00
95% CI		(-2.89, 6.89)
p-value [1]		0.470

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.111
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	21 (4.2%)	12 (2.4%)
Odds Ratio		0.56
95% CI		(0.27, 1.15)
Relative Risk		0.57
95% CI		(0.28, 1.15)
Risk Difference (%)		-1.80
95% CI		(-4.02, 0.41)
p-value [1]		0.156

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.111
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	12	11
Any event	6 (50.0%)	5 (45.5%)
Odds Ratio		0.83
95% CI		(0.16, 4.30)
Relative Risk		0.91
95% CI		(0.38, 2.15)
Risk Difference (%)		-4.55
95% CI		(-45.36, 36.27)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.111
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Infections and infestations		
Any event	3 (25.0%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-25.00
95% CI		(-49.50, -0.50)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.112
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	15	13
Any event	1 (6.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-6.67 (-19.29, 5.96)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.112
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	499	499
Any event	18 (3.6%)	12 (2.4%)
Odds Ratio		0.66
95% CI		(0.31, 1.38)
Relative Risk		0.67
95% CI		(0.32, 1.37)
Risk Difference (%)		-1.20
95% CI		(-3.32, 0.92)
p-value [1]		0.354

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.112
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	12	11
Any event	2 (16.7%)	1 (9.1%)
Odds Ratio		0.50
95% CI		(0.04, 6.44)
Relative Risk		0.55
95% CI		(0.06, 5.21)
Risk Difference (%)		-7.58
95% CI		(-34.65, 19.50)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.113
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	15	13
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.113
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	499	499
Any event	11 (2.2%)	9 (1.8%)
Odds Ratio		0.81
95% CI		(0.30, 2.19)
Relative Risk		0.82
95% CI		(0.34, 1.96)
Risk Difference (%)		-0.40
95% CI		(-2.14, 1.34)
p-value [1]		0.822

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.113
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	12	11
Any event	4 (33.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-33.33
95% CI		(-60.01, -6.66)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.114
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	15	13
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.114
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	499	499
Any event	2 (0.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.114
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	12	11
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.115
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	15	13
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.115
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	499	499
Any event	10 (2.0%)	9 (1.8%)
Odds Ratio		0.90
95% CI		(0.32, 2.48)
Relative Risk		0.90
95% CI		(0.37, 2.20)
Risk Difference (%)		-0.20
95% CI		(-1.90, 1.50)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 23.115
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	VIR-7831 500mg (N=523)
Number of subjects in subgroup	12	11
Any event	4 (33.3%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-33.33 (-60.01, -6.66)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.10
Summary and Analysis of Proportion of Subjects with Adverse Events by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	470	468
Any event	125 (26.6%)	117 (25.0%)
Odds Ratio		0.92
95% CI		(0.69, 1.23)
Relative Risk		0.94
95% CI		(0.76, 1.17)
Risk Difference (%)		-1.60
95% CI		(-7.19, 4.00)
p-value [1]		0.602

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.10
Summary and Analysis of Proportion of Subjects with Adverse Events by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	38 (8.1%)	17 (3.6%)
Odds Ratio		0.43
95% CI		(0.24, 0.77)
Relative Risk		0.45
95% CI		(0.26, 0.78)
Risk Difference (%)		-4.45
95% CI		(-7.44, -1.46)
p-value [1]		0.006

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.10
Summary and Analysis of Proportion of Subjects with Adverse Events by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	19 (4.0%)	3 (0.6%)
Odds Ratio		0.15
95% CI		(0.03, 0.53)
Relative Risk		0.16
95% CI		(0.05, 0.53)
Risk Difference (%)		-3.40
95% CI		(-5.32, -1.48)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.10
Summary and Analysis of Proportion of Subjects with Adverse Events by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	56	55
Any event	15 (26.8%)	16 (29.1%)
Odds Ratio		1.12
95% CI		(0.49, 2.57)
Relative Risk		1.09
95% CI		(0.60, 1.98)
Risk Difference (%)		2.31
95% CI		(-14.39, 19.00)
p-value [1]		0.835

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.10
Summary and Analysis of Proportion of Subjects with Adverse Events by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	10 (17.9%)	4 (7.3%)
Odds Ratio		0.36
95% CI		(0.11, 1.23)
Relative Risk		0.41
95% CI		(0.14, 1.22)
Risk Difference (%)		-10.58
95% CI		(-22.74, 1.57)
p-value [1]		0.152

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.10
Summary and Analysis of Proportion of Subjects with Adverse Events by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	3 (5.4%)	2 (3.6%)
Odds Ratio		0.67
95% CI		(0.11, 4.15)
Relative Risk		0.68
95% CI		(0.12, 3.91)
Risk Difference (%)		-1.72
95% CI		(-9.42, 5.98)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Protocol: 214367
Population: Safety

Table 33.11
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	470	468
Any event	27 (5.7%)	7 (1.5%)
Odds Ratio		0.25
95% CI		(0.09, 0.59)
Relative Risk		0.26
95% CI		(0.11, 0.59)
Risk Difference (%)		-4.25
95% CI		(-6.62, -1.88)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.11
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	20 (4.3%)	2 (0.4%)
Odds Ratio		0.10
95% CI		(0.01, 0.40)
Relative Risk		0.10
95% CI		(0.02, 0.43)
Risk Difference (%)		-3.83
95% CI		(-5.75, -1.91)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.11
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	17 (3.6%)	1 (0.2%)
Odds Ratio		0.06
95% CI		(0.00, 0.37)
Relative Risk		0.06
95% CI		(0.01, 0.44)
Risk Difference (%)		-3.40
95% CI		(-5.14, -1.66)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.11
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	56	55
Any event	8 (14.3%)	4 (7.3%)
Odds Ratio		0.47
95% CI		(0.13, 1.66)
Relative Risk		0.51
95% CI		(0.16, 1.59)
Risk Difference (%)		-7.01
95% CI		(-18.46, 4.44)
p-value [1]		0.361

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.11
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	5 (8.9%)	3 (5.5%)
Odds Ratio		0.59
95% CI		(0.13, 2.59)
Relative Risk		0.61
95% CI		(0.15, 2.43)
Risk Difference (%)		-3.47
95% CI		(-13.06, 6.11)
p-value [1]		0.717

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.11
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	3 (5.4%)	2 (3.6%)
Odds Ratio		0.67
95% CI		(0.11, 4.15)
Relative Risk		0.68
95% CI		(0.12, 3.91)
Risk Difference (%)		-1.72
95% CI		(-9.42, 5.98)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.12
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	470	468
Any event	3 (0.6%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.12
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	56	55
Any event	2 (3.6%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Protocol: 214367
Population: Safety

Table 33.13
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Age Group (<=70, >70)

Age group (years): <=70

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	470	468
Any event	5 (1.1%)	6 (1.3%)
Odds Ratio		1.21
95% CI		(0.30, 5.04)
Relative Risk		1.21
95% CI		(0.37, 3.92)
Risk Difference (%)		0.22
95% CI		(-1.16, 1.60)
p-value [1]		0.773

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Population: Safety

Table 33.13
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Age Group (<=70, >70)

Age group (years): >70

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	56	55
Any event	1 (1.8%)	1 (1.8%)
Odds Ratio		1.02
95% CI		(0.01, 81.39)
Relative Risk		1.02
95% CI		(0.07, 15.87)
Risk Difference (%)		0.03
95% CI		(-4.92, 4.98)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Protocol: 214367
Population: Safety

Table 33.14
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Age Group (<=70, >70)

Age group (years): <=70

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	470	468
Any event	0	1 (0.2%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Protocol: 214367
Population: Safety

Table 33.14
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Age Group (<=70, >70)

Age group (years): >70

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	56	55
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Protocol: 214367
Population: Safety

Table 33.15
Summary and Analysis of Proportion of Subjects with Serious Infusion-Related Reactions including Hypersensitivity by Age Group (<=70, >70)

No data to report

Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Protocol: 214367
Population: Safety

Table 33.16
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Age Group (<=70, >70)

Age group (years): <=70

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	470	468
Any event	0	1 (0.2%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Table 33.16
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Age Group (<=70, >70)

Age group (years): >70

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	56	55
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 33.17
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	470	468
Any event	2 (0.4%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Protocol: 214367
Population: Safety

Table 33.17
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	56	55
Any event	3 (5.4%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.18
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	470	468
Any event	25 (5.3%)	7 (1.5%)
Odds Ratio		0.27
95% CI		(0.10, 0.65)
Relative Risk		0.28
95% CI		(0.12, 0.64)
Risk Difference (%)		-3.82
95% CI		(-6.13, -1.52)
p-value [1]		0.002

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.18
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	19 (4.0%)	2 (0.4%)
Odds Ratio		0.10
95% CI		(0.01, 0.43)
Relative Risk		0.11
95% CI		(0.02, 0.45)
Risk Difference (%)		-3.62
95% CI		(-5.49, -1.74)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.18
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	17 (3.6%)	1 (0.2%)
Odds Ratio		0.06
95% CI		(0.00, 0.37)
Relative Risk		0.06
95% CI		(0.01, 0.44)
Risk Difference (%)		-3.40
95% CI		(-5.14, -1.66)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.18
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	56	55
Any event	6 (10.7%)	4 (7.3%)
Odds Ratio		0.65
95% CI		(0.17, 2.46)
Relative Risk		0.68
95% CI		(0.20, 2.27)
Risk Difference (%)		-3.44
95% CI		(-14.06, 7.18)
p-value [1]		0.743

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.18
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	3 (5.4%)	3 (5.5%)
Odds Ratio		1.02
95% CI		(0.20, 5.28)
Relative Risk		1.02
95% CI		(0.21, 4.83)
Risk Difference (%)		0.10
95% CI		(-8.32, 8.51)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.18
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	1 (1.8%)	2 (3.6%)
Odds Ratio		2.08
95% CI		(0.10, 124.64)
Relative Risk		2.04
95% CI		(0.19, 21.82)
Risk Difference (%)		1.85
95% CI		(-4.19, 7.89)
p-value [1]		0.619

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	96	98
Any event	24 (25.0%)	23 (23.5%)
Odds Ratio		0.92
95% CI		(0.48, 1.77)
Relative Risk		0.94
95% CI		(0.57, 1.54)
Risk Difference (%)		-1.53
95% CI		(-13.59, 10.53)
p-value [1]		0.868

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	4 (4.2%)	4 (4.1%)
Odds Ratio		0.98
95% CI		(0.24, 4.03)
Relative Risk		0.98
95% CI		(0.25, 3.81)
Risk Difference (%)		-0.09
95% CI		(-5.68, 5.51)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	0	1 (1.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		1.02
95% CI		(-0.97, 3.01)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	84	72
Any event	17 (20.2%)	22 (30.6%)
Odds Ratio		1.73
95% CI		(0.83, 3.60)
Relative Risk		1.51
95% CI		(0.87, 2.61)
Risk Difference (%)		10.32
95% CI		(-3.36, 23.99)
p-value [1]		0.144

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	7 (8.3%)	4 (5.6%)
Odds Ratio		0.65
95% CI		(0.18, 2.31)
Relative Risk		0.67
95% CI		(0.20, 2.19)
Risk Difference (%)		-2.78
95% CI		(-10.71, 5.15)
p-value [1]		0.549

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	0	1 (1.4%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		1.39
95% CI		(-1.31, 4.09)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	18 (31.0%)	18 (28.1%)
Odds Ratio		0.87
95% CI		(0.40, 1.89)
Relative Risk		0.91
95% CI		(0.52, 1.57)
Risk Difference (%)		-2.91
95% CI		(-19.13, 13.31)
p-value [1]		0.843

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	7 (12.1%)	2 (3.1%)
Odds Ratio		0.24
95% CI		(0.05, 1.18)
Relative Risk		0.26
95% CI		(0.06, 1.20)
Risk Difference (%)		-8.94
95% CI		(-18.35, 0.46)
p-value [1]		0.084

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	4 (6.9%)	1 (1.6%)
Odds Ratio		0.21
95% CI		(0.00, 2.28)
Relative Risk		0.23
95% CI		(0.03, 1.97)
Risk Difference (%)		-5.33
95% CI		(-12.53, 1.86)
p-value [1]		0.190

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	60	73
Any event	17 (28.3%)	17 (23.3%)
Odds Ratio		0.77
95% CI		(0.35, 1.68)
Relative Risk		0.82
95% CI		(0.46, 1.47)
Risk Difference (%)		-5.05
95% CI		(-20.01, 9.92)
p-value [1]		0.553

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	6 (10.0%)	1 (1.4%)
Odds Ratio		0.13
95% CI		(0.00, 1.09)
Relative Risk		0.14
95% CI		(0.02, 1.11)
Risk Difference (%)		-8.63
95% CI		(-16.68, -0.58)
p-value [1]		0.046

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (3.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.33
95% CI		(-7.88, 1.21)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	181	160
Any event	54 (29.8%)	36 (22.5%)
Odds Ratio		0.68
95% CI		(0.42, 1.11)
Relative Risk		0.75
95% CI		(0.52, 1.09)
Risk Difference (%)		-7.33
95% CI		(-16.62, 1.96)
p-value [1]		0.141

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	21 (11.6%)	8 (5.0%)
Odds Ratio		0.40
95% CI		(0.17, 0.93)
Relative Risk		0.43
95% CI		(0.20, 0.95)
Risk Difference (%)		-6.60
95% CI		(-12.36, -0.84)
p-value [1]		0.033

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.19
Summary and Analysis of Proportion of Subjects with Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	13 (7.2%)	2 (1.3%)
Odds Ratio		0.16
95% CI		(0.02, 0.74)
Relative Risk		0.17
95% CI		(0.04, 0.76)
Risk Difference (%)		-5.93
95% CI		(-10.07, -1.80)
p-value [1]		0.008

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Protocol: 214367
Population: Safety

Table 33.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	96	98
Any event	0	2 (2.0%)
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		2.04 (-0.76, 4.84)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	0	2 (2.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		2.04
95% CI		(-0.76, 4.84)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	0	1 (1.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		1.02
95% CI		(-0.97, 3.01)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	84	72
Any event	3 (3.6%)	1 (1.4%)
Odds Ratio		0.38
95% CI		(0.01, 4.88)
Relative Risk		0.39
95% CI		(0.04, 3.66)
Risk Difference (%)		-2.18
95% CI		(-6.98, 2.62)
p-value [1]		0.625

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	2 (2.4%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-2.38
95% CI		(-5.64, 0.88)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	5 (8.6%)	1 (1.6%)
Odds Ratio		0.17
95% CI		(0.00, 1.59)
Relative Risk		0.18
95% CI		(0.02, 1.51)
Risk Difference (%)		-7.06
95% CI		(-14.89, 0.78)
p-value [1]		0.102

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	5 (8.6%)	1 (1.6%)
Odds Ratio		0.17
95% CI		(0.00, 1.59)
Relative Risk		0.18
95% CI		(0.02, 1.51)
Risk Difference (%)		-7.06
95% CI		(-14.89, 0.78)
p-value [1]		0.102

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	4 (6.9%)	1 (1.6%)
Odds Ratio		0.21
95% CI		(0.00, 2.28)
Relative Risk		0.23
95% CI		(0.03, 1.97)
Risk Difference (%)		-5.33
95% CI		(-12.53, 1.86)
p-value [1]		0.190

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	60	73
Any event	3 (5.0%)	1 (1.4%)
Odds Ratio		0.26
95% CI		(0.00, 3.42)
Relative Risk		0.27
95% CI		(0.03, 2.57)
Risk Difference (%)		-3.63
95% CI		(-9.76, 2.50)
p-value [1]		0.328

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	2 (3.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.33
95% CI		(-7.88, 1.21)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (3.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.33
95% CI		(-7.88, 1.21)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	181	160
Any event	21 (11.6%)	4 (2.5%)
Odds Ratio		0.20
95% CI		(0.07, 0.58)
Relative Risk		0.22
95% CI		(0.08, 0.61)
Risk Difference (%)		-9.10
95% CI		(-14.36, -3.85)
p-value [1]		0.002

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	13 (7.2%)	2 (1.3%)
Odds Ratio		0.16
95% CI		(0.02, 0.74)
Relative Risk		0.17
95% CI		(0.04, 0.76)
Risk Difference (%)		-5.93
95% CI		(-10.07, -1.80)
p-value [1]		0.008

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.20
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	11 (6.1%)	1 (0.6%)
Odds Ratio		0.10
95% CI		(0.00, 0.69)
Relative Risk		0.10
95% CI		(0.01, 0.79)
Risk Difference (%)		-5.45
95% CI		(-9.14, -1.76)
p-value [1]		0.007

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.21
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	96	98
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.21
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	84	72
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.21
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	1 (1.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.21
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	60	73
Any event	1 (1.7%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.21
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	181	160
Any event	3 (1.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Protocol: 214367
Population: Safety

Table 33.22
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	96	98
Any event	0	2 (2.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 33.22
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	84	72
Any event	1 (1.2%)	1 (1.4%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 33.22
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	0	1 (1.6%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 33.22
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	60	73
Any event	3 (5.0%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Population: Safety

Table 33.22
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	181	160
Any event	2 (1.1%)	2 (1.3%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Population: Safety

Table 33.23
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Baseline Viral Load

No data to report

Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Protocol: 214367
Population: Safety

Table 33.24
Summary and Analysis of Proportion of Subjects with Serious Infusion-Related Reactions including Hypersensitivity by Baseline Viral Load

No data to report

Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Population: Safety

Table 33.25
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Baseline Viral Load

No data to report

Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Protocol: 214367
Population: Safety

Table 33.26
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	96	98
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.26
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	84	72
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.26
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	1 (1.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.26
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	60	73
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.26
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	181	160
Any event	4 (2.2%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Protocol: 214367
Population: Safety

Table 33.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	96	98
Any event	0	2 (2.0%)
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		2.04 (-0.76, 4.84)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	0	2 (2.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		2.04
95% CI		(-0.76, 4.84)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	0	1 (1.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		1.02
95% CI		(-0.97, 3.01)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Protocol: 214367
Population: Safety

Table 33.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	84	72
Any event	3 (3.6%)	1 (1.4%)
Odds Ratio		0.38
95% CI		(0.01, 4.88)
Relative Risk		0.39
95% CI		(0.04, 3.66)
Risk Difference (%)		-2.18
95% CI		(-6.98, 2.62)
p-value [1]		0.625

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	2 (2.4%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-2.38
95% CI		(-5.64, 0.88)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	4 (6.9%)	1 (1.6%)
Odds Ratio		0.21
95% CI		(0.00, 2.28)
Relative Risk		0.23
95% CI		(0.03, 1.97)
Risk Difference (%)		-5.33
95% CI		(-12.53, 1.86)
p-value [1]		0.190

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	4 (6.9%)	1 (1.6%)
Odds Ratio		0.21
95% CI		(0.00, 2.28)
Relative Risk		0.23
95% CI		(0.03, 1.97)
Risk Difference (%)		-5.33
95% CI		(-12.53, 1.86)
p-value [1]		0.190

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	3 (5.2%)	1 (1.6%)
Odds Ratio		0.29
95% CI		(0.01, 3.78)
Relative Risk		0.30
95% CI		(0.03, 2.82)
Risk Difference (%)		-3.61
95% CI		(-10.07, 2.85)
p-value [1]		0.346

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	60	73
Any event	3 (5.0%)	1 (1.4%)
Odds Ratio		0.26
95% CI		(0.00, 3.42)
Relative Risk		0.27
95% CI		(0.03, 2.57)
Risk Difference (%)		-3.63
95% CI		(-9.76, 2.50)
p-value [1]		0.328

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	2 (3.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.33
95% CI		(-7.88, 1.21)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (3.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.33
95% CI		(-7.88, 1.21)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	181	160
Any event	18 (9.9%)	4 (2.5%)
Odds Ratio		0.23
95% CI		(0.08, 0.70)
Relative Risk		0.25
95% CI		(0.09, 0.73)
Risk Difference (%)		-7.44
95% CI		(-12.43, -2.46)
p-value [1]		0.007

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	11 (6.1%)	2 (1.3%)
Odds Ratio		0.20
95% CI		(0.02, 0.92)
Relative Risk		0.21
95% CI		(0.05, 0.91)
Risk Difference (%)		-4.83
95% CI		(-8.71, -0.94)
p-value [1]		0.024

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.27
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	10 (5.5%)	1 (0.6%)
Odds Ratio		0.11
95% CI		(0.00, 0.77)
Relative Risk		0.11
95% CI		(0.01, 0.87)
Risk Difference (%)		-4.90
95% CI		(-8.45, -1.35)
p-value [1]		0.013

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Protocol: 214367
Population: Safety

Table 33.28
Summary and Analysis of Proportion of Subjects with Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	255	228
Any event	67 (26.3%)	49 (21.5%)
Odds Ratio		0.77
95% CI		(0.50, 1.17)
Relative Risk		0.82
95% CI		(0.59, 1.13)
Risk Difference (%)		-4.78
95% CI		(-12.37, 2.81)
p-value [1]		0.242

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.28
Summary and Analysis of Proportion of Subjects with Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	21 (8.2%)	11 (4.8%)
Odds Ratio		0.56
95% CI		(0.27, 1.20)
Relative Risk		0.59
95% CI		(0.29, 1.19)
Risk Difference (%)		-3.41
95% CI		(-7.78, 0.96)
p-value [1]		0.147

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.28
Summary and Analysis of Proportion of Subjects with Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	13 (5.1%)	3 (1.3%)
Odds Ratio		0.25
95% CI		(0.04, 0.92)
Relative Risk		0.26
95% CI		(0.07, 0.89)
Risk Difference (%)		-3.78
95% CI		(-6.86, -0.70)
p-value [1]		0.023

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.28
Summary and Analysis of Proportion of Subjects with Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	271	295
Any event	73 (26.9%)	84 (28.5%)
Odds Ratio		1.08
95% CI		(0.75, 1.56)
Relative Risk		1.06
95% CI		(0.81, 1.38)
Risk Difference (%)		1.54
95% CI		(-5.84, 8.91)
p-value [1]		0.708

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.28
Summary and Analysis of Proportion of Subjects with Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	27 (10.0%)	10 (3.4%)
Odds Ratio		0.32
95% CI		(0.15, 0.67)
Relative Risk		0.34
95% CI		(0.17, 0.69)
Risk Difference (%)		-6.57
95% CI		(-10.69, -2.45)
p-value [1]		0.002

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.28
Summary and Analysis of Proportion of Subjects with Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	9 (3.3%)	2 (0.7%)
Odds Ratio		0.20
95% CI		(0.02, 0.97)
Relative Risk		0.20
95% CI		(0.04, 0.94)
Risk Difference (%)		-2.64
95% CI		(-4.97, -0.31)
p-value [1]		0.031

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.29
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	255	228
Any event	20 (7.8%)	6 (2.6%)
Odds Ratio		0.32
95% CI		(0.13, 0.81)
Relative Risk		0.34
95% CI		(0.14, 0.82)
Risk Difference (%)		-5.21
95% CI		(-9.11, -1.31)
p-value [1]		0.015

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.29
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	14 (5.5%)	3 (1.3%)
Odds Ratio		0.23
95% CI		(0.04, 0.84)
Relative Risk		0.24
95% CI		(0.07, 0.82)
Risk Difference (%)		-4.17
95% CI		(-7.34, -1.01)
p-value [1]		0.014

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.29
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	11 (4.3%)	2 (0.9%)
Odds Ratio		0.20
95% CI		(0.02, 0.92)
Relative Risk		0.20
95% CI		(0.05, 0.91)
Risk Difference (%)		-3.44
95% CI		(-6.21, -0.66)
p-value [1]		0.024

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.29
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	271	295
Any event	15 (5.5%)	5 (1.7%)
Odds Ratio		0.29
95% CI		(0.08, 0.87)
Relative Risk		0.31
95% CI		(0.11, 0.83)
Risk Difference (%)		-3.84
95% CI		(-6.94, -0.74)
p-value [1]		0.021

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.29
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	11 (4.1%)	2 (0.7%)
Odds Ratio		0.16
95% CI		(0.02, 0.75)
Relative Risk		0.17
95% CI		(0.04, 0.75)
Risk Difference (%)		-3.38
95% CI		(-5.91, -0.85)
p-value [1]		0.010

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.29
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	9 (3.3%)	1 (0.3%)
Odds Ratio		0.10
95% CI		(0.00, 0.73)
Relative Risk		0.10
95% CI		(0.01, 0.80)
Risk Difference (%)		-2.98
95% CI		(-5.22, -0.75)
p-value [1]		0.009

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.30
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	255	228
Any event	3 (1.2%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.30
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	271	295
Any event	2 (0.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Protocol: 214367
Population: Safety

Table 33.31
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Gender

Gender: Male

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	255	228
Any event	3 (1.2%)	2 (0.9%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 33.31
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Gender

Gender: Female

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	271	295
Any event	3 (1.1%)	5 (1.7%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

Protocol: 214367
Population: Safety

Table 33.32
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Gender

Gender: Male

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	255	228
Any event	0	1 (0.4%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Table 33.32
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Gender

Gender: Female

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	271	295
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Protocol: 214367
Population: Safety

Table 33.33
Summary and Analysis of Proportion of Subjects with Serious Infusion-Related Reactions including Hypersensitivity by Gender

No data to report

Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Protocol: 214367
Population: Safety

Table 33.34
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Gender

Gender: Male

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	255	228
Any event	0	1 (0.4%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Table 33.34
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Gender

Gender: Female

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	271	295
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Protocol: 214367
Population: Safety

Table 33.35
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	255	228
Any event	4 (1.6%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Protocol: 214367
Population: Safety

Table 33.35
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	271	295
Any event	1 (0.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.36
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	255	228
Any event	17 (6.7%)	6 (2.6%)
Odds Ratio		0.38
95% CI		(0.15, 0.98)
Relative Risk		0.39
95% CI		(0.16, 0.98)
Risk Difference (%)		-4.04
95% CI		(-7.74, -0.34)
p-value [1]		0.053

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.36
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	12 (4.7%)	3 (1.3%)
Odds Ratio		0.27
95% CI		(0.05, 1.02)
Relative Risk		0.28
95% CI		(0.08, 0.98)
Risk Difference (%)		-3.39
95% CI		(-6.38, -0.40)
p-value [1]		0.037

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.36
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	10 (3.9%)	2 (0.9%)
Odds Ratio		0.22
95% CI		(0.02, 1.04)
Relative Risk		0.22
95% CI		(0.05, 1.01)
Risk Difference (%)		-3.04
95% CI		(-5.72, -0.37)
p-value [1]		0.040

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.36
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	271	295
Any event	14 (5.2%)	5 (1.7%)
Odds Ratio		0.32
95% CI		(0.09, 0.95)
Relative Risk		0.33
95% CI		(0.12, 0.90)
Risk Difference (%)		-3.47
95% CI		(-6.49, -0.45)
p-value [1]		0.034

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.36
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	10 (3.7%)	2 (0.7%)
Odds Ratio		0.18
95% CI		(0.02, 0.85)
Relative Risk		0.18
95% CI		(0.04, 0.83)
Risk Difference (%)		-3.01
95% CI		(-5.44, -0.58)
p-value [1]		0.018

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.36
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	8 (3.0%)	1 (0.3%)
Odds Ratio		0.11
95% CI		(0.00, 0.85)
Relative Risk		0.11
95% CI		(0.01, 0.91)
Risk Difference (%)		-2.61
95% CI		(-4.73, -0.49)
p-value [1]		0.017

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Protocol: 214367
Population: Safety

Table 33.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	306	290
Any event	74 (24.2%)	68 (23.4%)
Odds Ratio		0.96
95% CI		(0.66, 1.40)
Relative Risk		0.97
95% CI		(0.73, 1.29)
Risk Difference (%)		-0.73
95% CI		(-7.58, 6.11)
p-value [1]		0.848

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	22 (7.2%)	4 (1.4%)
Odds Ratio		0.18
95% CI		(0.04, 0.54)
Relative Risk		0.19
95% CI		(0.07, 0.55)
Risk Difference (%)		-5.81
95% CI		(-9.00, -2.62)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	10 (3.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.27
95% CI		(-5.26, -1.28)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	151	176
Any event	41 (27.2%)	49 (27.8%)
Odds Ratio		1.04
95% CI		(0.64, 1.68)
Relative Risk		1.03
95% CI		(0.72, 1.46)
Risk Difference (%)		0.69
95% CI		(-9.02, 10.39)
p-value [1]		0.902

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	15 (9.9%)	11 (6.3%)
Odds Ratio		0.60
95% CI		(0.27, 1.36)
Relative Risk		0.63
95% CI		(0.30, 1.33)
Risk Difference (%)		-3.68
95% CI		(-9.65, 2.28)
p-value [1]		0.228

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	7 (4.6%)	3 (1.7%)
Odds Ratio		0.36
95% CI		(0.06, 1.60)
Relative Risk		0.37
95% CI		(0.10, 1.40)
Risk Difference (%)		-2.93
95% CI		(-6.79, 0.93)
p-value [1]		0.197

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	69	57
Any event	25 (36.2%)	16 (28.1%)
Odds Ratio		0.69
95% CI		(0.32, 1.47)
Relative Risk		0.77
95% CI		(0.46, 1.30)
Risk Difference (%)		-8.16
95% CI		(-24.43, 8.11)
p-value [1]		0.348

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	11 (15.9%)	6 (10.5%)
Odds Ratio		0.62
95% CI		(0.21, 1.80)
Relative Risk		0.66
95% CI		(0.26, 1.67)
Risk Difference (%)		-5.42
95% CI		(-17.17, 6.33)
p-value [1]		0.440

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.37
Summary and Analysis of Proportion of Subjects with Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	5 (7.2%)	2 (3.5%)
Odds Ratio		0.47
95% CI		(0.09, 2.49)
Relative Risk		0.48
95% CI		(0.10, 2.40)
Risk Difference (%)		-3.74
95% CI		(-11.50, 4.02)
p-value [1]		0.456

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.38
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	306	290
Any event	18 (5.9%)	2 (0.7%)
Odds Ratio		0.11
95% CI		(0.01, 0.47)
Relative Risk		0.12
95% CI		(0.03, 0.50)
Risk Difference (%)		-5.19
95% CI		(-8.00, -2.39)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.38
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	10 (3.3%)	1 (0.3%)
Odds Ratio		0.10
95% CI		(0.00, 0.73)
Relative Risk		0.11
95% CI		(0.01, 0.82)
Risk Difference (%)		-2.92
95% CI		(-5.03, -0.82)
p-value [1]		0.012

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.38
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	9 (2.9%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.38
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	151	176
Any event	11 (7.3%)	4 (2.3%)
Odds Ratio		0.30
95% CI		(0.09, 0.95)
Relative Risk		0.31
95% CI		(0.10, 0.96)
Risk Difference (%)		-5.01
95% CI		(-9.71, -0.32)
p-value [1]		0.036

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.38
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	9 (6.0%)	2 (1.1%)
Odds Ratio		0.18
95% CI		(0.02, 0.90)
Relative Risk		0.19
95% CI		(0.04, 0.87)
Risk Difference (%)		-4.82
95% CI		(-8.91, -0.74)
p-value [1]		0.027

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.38
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	7 (4.6%)	1 (0.6%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.38
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	69	57
Any event	6 (8.7%)	5 (8.8%)
Odds Ratio		1.01
95% CI		(0.29, 3.50)
Relative Risk		1.01
95% CI		(0.32, 3.13)
Risk Difference (%)		0.08
95% CI		(-9.83, 9.98)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.38
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	6 (8.7%)	2 (3.5%)
Odds Ratio		0.38
95% CI		(0.07, 1.97)
Relative Risk		0.40
95% CI		(0.08, 1.92)
Risk Difference (%)		-5.19
95% CI		(-13.37, 3.00)
p-value [1]		0.292

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.38
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	4 (5.8%)	2 (3.5%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Protocol: 214367
Population: Safety

Table 33.39
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	306	290
Any event	1 (0.3%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.39
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	151	176
Any event	3 (2.0%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.39
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	69	57
Any event	1 (1.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.40
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Number of Risk Factors

Number of risk factors: <=1

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	306	290
Any event	4 (1.3%)	2 (0.7%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 33.40
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Number of Risk Factors

Number of risk factors: 2

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	151	176
Any event	1 (0.7%)	3 (1.7%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Population: Safety

Table 33.40
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Number of Risk Factors

Number of risk factors: >=3

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	69	57
Any event	1 (1.4%)	2 (3.5%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 33.41
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Number of Risk Factors

Number of risk factors: <=1

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	306	290
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Protocol: 214367
Population: Safety

Table 33.41
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Number of Risk Factors

Number of risk factors: 2

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	151	176
Any event	0	1 (0.6%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 33.41
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Number of Risk Factors

Number of risk factors: >=3

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	69	57
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Protocol: 214367
Population: Safety

Table 33.42
Summary and Analysis of Proportion of Subjects with Serious Infusion-Related Reactions including Hypersensitivity by Number of Risk Factors

No data to report

Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Protocol: 214367
Population: Safety

Table 33.43
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Number of Risk Factors

Number of risk factors: <=1

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	306	290
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Table 33.43
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Number of Risk Factors

Number of risk factors: 2

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	151	176
Any event	0	1 (0.6%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 33.43
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Number of Risk Factors

Number of risk factors: >=3

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	69	57
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Protocol: 214367
Population: Safety

Table 33.44
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	306	290
Any event	1 (0.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.44
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	151	176
Any event	3 (2.0%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.44
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	69	57
Any event	1 (1.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	306	290
Any event	18 (5.9%)	2 (0.7%)
Odds Ratio		0.11
95% CI		(0.01, 0.47)
Relative Risk		0.12
95% CI		(0.03, 0.50)
Risk Difference (%)		-5.19
95% CI		(-8.00, -2.39)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	10 (3.3%)	1 (0.3%)
Odds Ratio		0.10
95% CI		(0.00, 0.73)
Relative Risk		0.11
95% CI		(0.01, 0.82)
Risk Difference (%)		-2.92
95% CI		(-5.03, -0.82)
p-value [1]		0.012

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	9 (2.9%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	151	176
Any event	8 (5.3%)	4 (2.3%)
Odds Ratio		0.42
95% CI		(0.12, 1.41)
Relative Risk		0.43
95% CI		(0.13, 1.40)
Risk Difference (%)		-3.03
95% CI		(-7.22, 1.17)
p-value [1]		0.238

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	7 (4.6%)	2 (1.1%)
Odds Ratio		0.24
95% CI		(0.02, 1.27)
Relative Risk		0.25
95% CI		(0.05, 1.16)
Risk Difference (%)		-3.50
95% CI		(-7.20, 0.20)
p-value [1]		0.087

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	5 (3.3%)	1 (0.6%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	69	57
Any event	5 (7.2%)	5 (8.8%)
Odds Ratio		1.23
95% CI		(0.34, 4.48)
Relative Risk		1.21
95% CI		(0.37, 3.97)
Risk Difference (%)		1.53
95% CI		(-8.03, 11.08)
p-value [1]		0.755

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	5 (7.2%)	2 (3.5%)
Odds Ratio		0.47
95% CI		(0.09, 2.49)
Relative Risk		0.48
95% CI		(0.10, 2.40)
Risk Difference (%)		-3.74
95% CI		(-11.50, 4.02)
p-value [1]		0.456

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.45
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	4 (5.8%)	2 (3.5%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Protocol: 214367
Population: Safety

Table 33.46
Summary and Analysis of Proportion of Subjects with Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	237	240
Any event	57 (24.1%)	67 (27.9%)
Odds Ratio		1.22
95% CI		(0.81, 1.84)
Relative Risk		1.16
95% CI		(0.86, 1.57)
Risk Difference (%)		3.87
95% CI		(-4.00, 11.73)
p-value [1]		0.350

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.46
Summary and Analysis of Proportion of Subjects with Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	18 (7.6%)	9 (3.8%)
Odds Ratio		0.47
95% CI		(0.21, 1.08)
Relative Risk		0.49
95% CI		(0.23, 1.08)
Risk Difference (%)		-3.84
95% CI		(-7.99, 0.30)
p-value [1]		0.077

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.46
Summary and Analysis of Proportion of Subjects with Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	8 (3.4%)	2 (0.8%)
Odds Ratio		0.24
95% CI		(0.02, 1.23)
Relative Risk		0.25
95% CI		(0.05, 1.15)
Risk Difference (%)		-2.54
95% CI		(-5.11, 0.03)
p-value [1]		0.062

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.46
Summary and Analysis of Proportion of Subjects with Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	212	219
Any event	60 (28.3%)	48 (21.9%)
Odds Ratio		0.71
95% CI		(0.46, 1.10)
Relative Risk		0.77
95% CI		(0.56, 1.08)
Risk Difference (%)		-6.38
95% CI		(-14.56, 1.79)
p-value [1]		0.149

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.46
Summary and Analysis of Proportion of Subjects with Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	19 (9.0%)	7 (3.2%)
Odds Ratio		0.34
95% CI		(0.14, 0.82)
Relative Risk		0.36
95% CI		(0.15, 0.83)
Risk Difference (%)		-5.77
95% CI		(-10.26, -1.27)
p-value [1]		0.015

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.46
Summary and Analysis of Proportion of Subjects with Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	10 (4.7%)	2 (0.9%)
Odds Ratio		0.19
95% CI		(0.02, 0.89)
Relative Risk		0.19
95% CI		(0.04, 0.87)
Risk Difference (%)		-3.80
95% CI		(-6.92, -0.68)
p-value [1]		0.019

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.47
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	237	240
Any event	11 (4.6%)	5 (2.1%)
Odds Ratio		0.44
95% CI		(0.15, 1.28)
Relative Risk		0.45
95% CI		(0.16, 1.27)
Risk Difference (%)		-2.56
95% CI		(-5.79, 0.67)
p-value [1]		0.135

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.47
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	8 (3.4%)	3 (1.3%)
Odds Ratio		0.36
95% CI		(0.06, 1.54)
Relative Risk		0.37
95% CI		(0.10, 1.38)
Risk Difference (%)		-2.13
95% CI		(-4.82, 0.57)
p-value [1]		0.140

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.47
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	7 (3.0%)	2 (0.8%)
Odds Ratio		0.28
95% CI		(0.03, 1.47)
Relative Risk		0.28
95% CI		(0.06, 1.34)
Risk Difference (%)		-2.12
95% CI		(-4.56, 0.32)
p-value [1]		0.105

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.47
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	212	219
Any event	14 (6.6%)	5 (2.3%)
Odds Ratio		0.33
95% CI		(0.12, 0.93)
Relative Risk		0.35
95% CI		(0.13, 0.94)
Risk Difference (%)		-4.32
95% CI		(-8.21, -0.44)
p-value [1]		0.035

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.47
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	10 (4.7%)	2 (0.9%)
Odds Ratio		0.19
95% CI		(0.02, 0.89)
Relative Risk		0.19
95% CI		(0.04, 0.87)
Risk Difference (%)		-3.80
95% CI		(-6.92, -0.68)
p-value [1]		0.019

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.47
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	9 (4.2%)	1 (0.5%)
Odds Ratio		0.10
95% CI		(0.00, 0.76)
Relative Risk		0.11
95% CI		(0.01, 0.84)
Risk Difference (%)		-3.79
95% CI		(-6.65, -0.93)
p-value [1]		0.010

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.48
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	237	240
Any event	3 (1.3%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.48
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	212	219
Any event	2 (0.9%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Protocol: 214367
Population: Safety

Table 33.49
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	237	240
Any event	2 (0.8%)	2 (0.8%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 33.49
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	212	219
Any event	2 (0.9%)	5 (2.3%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Protocol: 214367
Population: Safety

Table 33.50
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	237	240
Any event	0	1 (0.4%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Table 33.50
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	212	219
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Population: Safety

Table 33.51
Summary and Analysis of Proportion of Subjects with Serious Infusion-Related Reactions including Hypersensitivity by Patient Reported Symptom Severity

No data to report

Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Population: Safety

Table 33.52
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	237	240
Any event	0	1 (0.4%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Table 33.52
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	212	219
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Protocol: 214367
Population: Safety

Table 33.53
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	237	240
Any event	2 (0.8%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.53
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	212	219
Any event	2 (0.9%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Protocol: 214367
Population: Safety

Table 33.54
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	237	240
Any event	9 (3.8%)	5 (2.1%)
Odds Ratio		0.54
95% CI		(0.18, 1.63)
Relative Risk		0.55
95% CI		(0.19, 1.61)
Risk Difference (%)		-1.71
95% CI		(-4.75, 1.32)
p-value [1]		0.292

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.54
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	6 (2.5%)	3 (1.3%)
Odds Ratio		0.49
95% CI		(0.08, 2.32)
Relative Risk		0.49
95% CI		(0.12, 1.95)
Risk Difference (%)		-1.28
95% CI		(-3.73, 1.16)
p-value [1]		0.337

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.54
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	6 (2.5%)	2 (0.8%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.54
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	212	219
Any event	12 (5.7%)	5 (2.3%)
Odds Ratio		0.39
95% CI		(0.13, 1.13)
Relative Risk		0.40
95% CI		(0.14, 1.13)
Risk Difference (%)		-3.38
95% CI		(-7.06, 0.31)
p-value [1]		0.086

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.54
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	9 (4.2%)	2 (0.9%)
Odds Ratio		0.21
95% CI		(0.02, 1.02)
Relative Risk		0.22
95% CI		(0.05, 0.98)
Risk Difference (%)		-3.33
95% CI		(-6.32, -0.34)
p-value [1]		0.034

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.54
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	8 (3.8%)	1 (0.5%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	15	13
Any event	8 (53.3%)	6 (46.2%)
Odds Ratio		0.75
95% CI		(0.17, 3.33)
Relative Risk		0.87
95% CI		(0.41, 1.84)
Risk Difference (%)		-7.18
95% CI		(-44.22, 29.86)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	4 (26.7%)	1 (7.7%)
Odds Ratio		0.23
95% CI		(0.02, 2.38)
Relative Risk		0.29
95% CI		(0.04, 2.27)
Risk Difference (%)		-18.97
95% CI		(-45.63, 7.68)
p-value [1]		0.334

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (13.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-13.33
95% CI		(-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	499	499
Any event	125 (25.1%)	121 (24.2%)
Odds Ratio		0.96
95% CI		(0.72, 1.28)
Relative Risk		0.97
95% CI		(0.78, 1.20)
Risk Difference (%)		-0.80
95% CI		(-6.15, 4.55)
p-value [1]		0.826

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	39 (7.8%)	20 (4.0%)
Odds Ratio		0.49
95% CI		(0.28, 0.86)
Relative Risk		0.51
95% CI		(0.30, 0.87)
Risk Difference (%)		-3.81
95% CI		(-6.72, -0.89)
p-value [1]		0.016

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	17 (3.4%)	5 (1.0%)
Odds Ratio		0.29
95% CI		(0.08, 0.82)
Relative Risk		0.29
95% CI		(0.11, 0.79)
Risk Difference (%)		-2.40
95% CI		(-4.22, -0.59)
p-value [1]		0.016

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	12	11
Any event	7 (58.3%)	6 (54.5%)
Odds Ratio		0.86
95% CI		(0.16, 4.47)
Relative Risk		0.94
95% CI		(0.45, 1.92)
Risk Difference (%)		-3.79
95% CI		(-44.33, 36.76)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	5 (41.7%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-41.67
95% CI		(-69.56, -13.77)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.55
Summary and Analysis of Proportion of Subjects with Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	3 (25.0%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-25.00
95% CI		(-49.50, -0.50)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	15	13
Any event	2 (13.3%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-13.33 (-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	2 (13.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-13.33
95% CI		(-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (13.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-13.33
95% CI		(-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	499	499
Any event	28 (5.6%)	11 (2.2%)
Odds Ratio		0.38
95% CI		(0.19, 0.77)
Relative Risk		0.39
95% CI		(0.20, 0.78)
Risk Difference (%)		-3.41
95% CI		(-5.80, -1.01)
p-value [1]		0.009

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	19 (3.8%)	5 (1.0%)
Odds Ratio		0.26
95% CI		(0.07, 0.72)
Relative Risk		0.26
95% CI		(0.10, 0.70)
Risk Difference (%)		-2.81
95% CI		(-4.70, -0.91)
p-value [1]		0.006

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	15 (3.0%)	3 (0.6%)
Odds Ratio		0.20
95% CI		(0.04, 0.70)
Relative Risk		0.20
95% CI		(0.06, 0.69)
Risk Difference (%)		-2.40
95% CI		(-4.05, -0.76)
p-value [1]		0.008

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	12	11
Any event	5 (41.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-41.67 (-69.56, -13.77)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	4 (33.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-33.33
95% CI		(-60.01, -6.66)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.56
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	3 (25.0%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-25.00
95% CI		(-49.50, -0.50)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Protocol: 214367
Population: Safety

Table 33.57
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	15	13
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.57
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	499	499
Any event	5 (1.0%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.57
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	12	11
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.58
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Region

Region: Europe

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	15	13
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 33.58
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Region

Region: North America

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	499	499
Any event	5 (1.0%)	7 (1.4%)
Odds Ratio		1.41
95% CI		(0.38, 5.65)
Relative Risk		1.40
95% CI		(0.45, 4.38)
Risk Difference (%)		0.40
95% CI		(-0.95, 1.75)
p-value [1]		0.774

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 33.58
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Region

Region: South America

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	12	11
Any event	1 (8.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-8.33
95% CI		(-23.97, 7.30)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Protocol: 214367
Population: Safety

Table 33.59
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Region

Region: Europe

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	15	13
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Table 33.59
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Region

Region: North America

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	499	499
Any event	0	1 (0.2%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 33.59
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Region

Region: South America

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	12	11
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 33.60
Summary and Analysis of Proportion of Subjects with Serious Infusion-Related Reactions including Hypersensitivity by Region

No data to report

Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Protocol: 214367
Population: Safety

Table 33.61
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Region

Region: Europe

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	15	13
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Population: Safety

Table 33.61
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Region

Region: North America

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	499	499
Any event	0	1 (0.2%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Table 33.61
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Region

Region: South America

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	12	11
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Population: Safety

Table 33.62
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	15	13
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.62
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	499	499
Any event	4 (0.8%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.62
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	12	11
Any event	1 (8.3%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	15	13
Any event	2 (13.3%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-13.33 (-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	2 (13.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-13.33
95% CI		(-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (13.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-13.33
95% CI		(-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	499	499
Any event	24 (4.8%)	11 (2.2%)
Odds Ratio		0.45
95% CI		(0.22, 0.92)
Relative Risk		0.46
95% CI		(0.23, 0.93)
Risk Difference (%)		-2.61
95% CI		(-4.88, -0.33)
p-value [1]		0.038

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	16 (3.2%)	5 (1.0%)
Odds Ratio		0.31
95% CI		(0.09, 0.88)
Relative Risk		0.31
95% CI		(0.12, 0.85)
Risk Difference (%)		-2.20
95% CI		(-3.98, -0.43)
p-value [1]		0.026

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	13 (2.6%)	3 (0.6%)
Odds Ratio		0.23
95% CI		(0.04, 0.83)
Relative Risk		0.23
95% CI		(0.07, 0.80)
Risk Difference (%)		-2.00
95% CI		(-3.56, -0.45)
p-value [1]		0.021

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	12	11
Any event	5 (41.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-41.67 (-69.56, -13.77)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	4 (33.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-33.33
95% CI		(-60.01, -6.66)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.63
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	3 (25.0%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-25.00
95% CI		(-49.50, -0.50)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.74
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	470	468
Any event	40 (8.5%)	18 (3.8%)
Odds Ratio		0.43
95% CI		(0.24, 0.76)
Relative Risk		0.45
95% CI		(0.26, 0.78)
Risk Difference (%)		-4.66
95% CI		(-7.73, -1.60)
p-value [1]		0.005

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.74
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	21 (4.5%)	2 (0.4%)
Odds Ratio		0.09
95% CI		(0.01, 0.38)
Relative Risk		0.10
95% CI		(0.02, 0.41)
Risk Difference (%)		-4.04
95% CI		(-6.00, -2.08)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.74
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	18 (3.8%)	1 (0.2%)
Odds Ratio		0.05
95% CI		(0.00, 0.34)
Relative Risk		0.06
95% CI		(0.01, 0.42)
Risk Difference (%)		-3.62
95% CI		(-5.40, -1.83)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.74
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	56	55
Any event	5 (8.9%)	4 (7.3%)
Odds Ratio		0.80
95% CI		(0.20, 3.15)
Relative Risk		0.81
95% CI		(0.23, 2.87)
Risk Difference (%)		-1.66
95% CI		(-11.80, 8.49)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.74
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	4 (7.1%)	3 (5.5%)
Odds Ratio		0.75
95% CI		(0.16, 3.52)
Relative Risk		0.76
95% CI		(0.18, 3.26)
Risk Difference (%)		-1.69
95% CI		(-10.72, 7.34)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Protocol: 214367
Population: Safety

Table 33.74
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	3 (5.4%)	2 (3.6%)
Odds Ratio		0.67
95% CI		(0.11, 4.15)
Relative Risk		0.68
95% CI		(0.12, 3.91)
Risk Difference (%)		-1.72
95% CI		(-9.42, 5.98)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Protocol: 214367
Population: Safety

Table 33.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	96	98
Any event	4 (4.2%)	4 (4.1%)
Odds Ratio		0.98
95% CI		(0.24, 4.03)
Relative Risk		0.98
95% CI		(0.25, 3.81)
Risk Difference (%)		-0.09
95% CI		(-5.68, 5.51)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	0	2 (2.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		2.04
95% CI		(-0.76, 4.84)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	0	1 (1.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		1.02
95% CI		(-0.97, 3.01)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	84	72
Any event	3 (3.6%)	3 (4.2%)
Odds Ratio		1.17
95% CI		(0.23, 6.00)
Relative Risk		1.17
95% CI		(0.24, 5.60)
Risk Difference (%)		0.60
95% CI		(-5.49, 6.68)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	6 (10.3%)	1 (1.6%)
Odds Ratio		0.14
95% CI		(0.00, 1.21)
Relative Risk		0.15
95% CI		(0.02, 1.22)
Risk Difference (%)		-8.78
95% CI		(-17.19, -0.38)
p-value [1]		0.053

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	5 (8.6%)	1 (1.6%)
Odds Ratio		0.17
95% CI		(0.00, 1.59)
Relative Risk		0.18
95% CI		(0.02, 1.51)
Risk Difference (%)		-7.06
95% CI		(-14.89, 0.78)
p-value [1]		0.102

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	4 (6.9%)	1 (1.6%)
Odds Ratio		0.21
95% CI		(0.00, 2.28)
Relative Risk		0.23
95% CI		(0.03, 1.97)
Risk Difference (%)		-5.33
95% CI		(-12.53, 1.86)
p-value [1]		0.190

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	60	73
Any event	4 (6.7%)	6 (8.2%)
Odds Ratio		1.25
95% CI		(0.34, 4.67)
Relative Risk		1.23
95% CI		(0.36, 4.17)
Risk Difference (%)		1.55
95% CI		(-7.37, 10.47)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	2 (3.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.33
95% CI		(-7.88, 1.21)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (3.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.33
95% CI		(-7.88, 1.21)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	181	160
Any event	24 (13.3%)	6 (3.8%)
Odds Ratio		0.25
95% CI		(0.10, 0.64)
Relative Risk		0.28
95% CI		(0.12, 0.67)
Risk Difference (%)		-9.51
95% CI		(-15.26, -3.76)
p-value [1]		0.002

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	15 (8.3%)	2 (1.3%)
Odds Ratio		0.14
95% CI		(0.02, 0.62)
Relative Risk		0.15
95% CI		(0.04, 0.65)
Risk Difference (%)		-7.04
95% CI		(-11.41, -2.67)
p-value [1]		0.003

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.75
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	12 (6.6%)	1 (0.6%)
Odds Ratio		0.09
95% CI		(0.00, 0.61)
Relative Risk		0.09
95% CI		(0.01, 0.72)
Risk Difference (%)		-6.00
95% CI		(-9.83, -2.18)
p-value [1]		0.004

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Protocol: 214367
Population: Safety

Table 33.76
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	255	228
Any event	26 (10.2%)	10 (4.4%)
Odds Ratio		0.40
95% CI		(0.19, 0.86)
Relative Risk		0.43
95% CI		(0.21, 0.87)
Risk Difference (%)		-5.81
95% CI		(-10.38, -1.24)
p-value [1]		0.016

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.76
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	15 (5.9%)	2 (0.9%)
Odds Ratio		0.14
95% CI		(0.02, 0.62)
Relative Risk		0.15
95% CI		(0.03, 0.65)
Risk Difference (%)		-5.01
95% CI		(-8.14, -1.87)
p-value [1]		0.003

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.76
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	12 (4.7%)	2 (0.9%)
Odds Ratio		0.18
95% CI		(0.02, 0.82)
Relative Risk		0.19
95% CI		(0.04, 0.82)
Risk Difference (%)		-3.83
95% CI		(-6.70, -0.96)
p-value [1]		0.014

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.76
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	271	295
Any event	19 (7.0%)	12 (4.1%)
Odds Ratio		0.56
95% CI		(0.27, 1.18)
Relative Risk		0.58
95% CI		(0.29, 1.17)
Risk Difference (%)		-2.94
95% CI		(-6.73, 0.84)
p-value [1]		0.142

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.76
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	10 (3.7%)	3 (1.0%)
Odds Ratio		0.27
95% CI		(0.05, 1.06)
Relative Risk		0.28
95% CI		(0.08, 0.99)
Risk Difference (%)		-2.67
95% CI		(-5.19, -0.15)
p-value [1]		0.048

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Table 33.76
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	9 (3.3%)	1 (0.3%)
Odds Ratio		0.10
95% CI		(0.00, 0.73)
Relative Risk		0.10
95% CI		(0.01, 0.80)
Risk Difference (%)		-2.98
95% CI		(-5.22, -0.75)
p-value [1]		0.009

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	306	290
Any event	23 (7.5%)	7 (2.4%)
Odds Ratio		0.30
95% CI		(0.13, 0.72)
Relative Risk		0.32
95% CI		(0.14, 0.74)
Risk Difference (%)		-5.10
95% CI		(-8.54, -1.66)
p-value [1]		0.005

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	11 (3.6%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.59
95% CI		(-5.68, -1.51)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	9 (2.9%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	151	176
Any event	11 (7.3%)	10 (5.7%)
Odds Ratio		0.77
95% CI		(0.32, 1.86)
Relative Risk		0.78
95% CI		(0.34, 1.79)
Risk Difference (%)		-1.60
95% CI		(-6.98, 3.77)
p-value [1]		0.653

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	7 (4.6%)	3 (1.7%)
Odds Ratio		0.36
95% CI		(0.06, 1.60)
Relative Risk		0.37
95% CI		(0.10, 1.40)
Risk Difference (%)		-2.93
95% CI		(-6.79, 0.93)
p-value [1]		0.197

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	7 (4.6%)	1 (0.6%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	69	57
Any event	11 (15.9%)	5 (8.8%)
Odds Ratio		0.51
95% CI		(0.17, 1.56)
Relative Risk		0.55
95% CI		(0.20, 1.49)
Risk Difference (%)		-7.17
95% CI		(-18.51, 4.17)
p-value [1]		0.288

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	7 (10.1%)	2 (3.5%)
Odds Ratio		0.32
95% CI		(0.06, 1.62)
Relative Risk		0.35
95% CI		(0.07, 1.60)
Risk Difference (%)		-6.64
95% CI		(-15.21, 1.94)
p-value [1]		0.183

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.77
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	5 (7.2%)	2 (3.5%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.78
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	237	240
Any event	16 (6.8%)	5 (2.1%)
Odds Ratio		0.29
95% CI		(0.11, 0.82)
Relative Risk		0.31
95% CI		(0.11, 0.83)
Risk Difference (%)		-4.67
95% CI		(-8.34, -1.00)
p-value [1]		0.015

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.78
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	9 (3.8%)	2 (0.8%)
Odds Ratio		0.21
95% CI		(0.02, 1.05)
Relative Risk		0.22
95% CI		(0.05, 1.00)
Risk Difference (%)		-2.96
95% CI		(-5.66, -0.27)
p-value [1]		0.036

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.78
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	8 (3.4%)	2 (0.8%)
Odds Ratio		0.24
95% CI		(0.02, 1.23)
Relative Risk		0.25
95% CI		(0.05, 1.15)
Risk Difference (%)		-2.54
95% CI		(-5.11, 0.03)
p-value [1]		0.062

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.78
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	212	219
Any event	21 (9.9%)	15 (6.8%)
Odds Ratio		0.67
95% CI		(0.33, 1.34)
Relative Risk		0.69
95% CI		(0.37, 1.30)
Risk Difference (%)		-3.06
95% CI		(-8.29, 2.17)
p-value [1]		0.298

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.78
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	11 (5.2%)	3 (1.4%)
Odds Ratio		0.25
95% CI		(0.04, 0.98)
Relative Risk		0.26
95% CI		(0.07, 0.93)
Risk Difference (%)		-3.82
95% CI		(-7.18, -0.46)
p-value [1]		0.030

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.78
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	10 (4.7%)	1 (0.5%)
Odds Ratio		0.09
95% CI		(0.00, 0.66)
Relative Risk		0.10
95% CI		(0.01, 0.75)
Risk Difference (%)		-4.26
95% CI		(-7.25, -1.27)
p-value [1]		0.006

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Protocol: 214367
Population: Safety

Table 33.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	15	13
Any event	2 (13.3%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-13.33 (-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	2 (13.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-13.33
95% CI		(-30.54, 3.87)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	1 (6.7%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-6.67
95% CI		(-19.29, 5.96)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 33.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	499	499
Any event	39 (7.8%)	21 (4.2%)
Odds Ratio		0.52
95% CI		(0.30, 0.89)
Relative Risk		0.54
95% CI		(0.32, 0.90)
Risk Difference (%)		-3.61
95% CI		(-6.55, -0.67)
p-value [1]		0.023

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	19 (3.8%)	5 (1.0%)
Odds Ratio		0.26
95% CI		(0.07, 0.72)
Relative Risk		0.26
95% CI		(0.10, 0.70)
Risk Difference (%)		-2.81
95% CI		(-4.70, -0.91)
p-value [1]		0.006

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	17 (3.4%)	3 (0.6%)
Odds Ratio		0.17
95% CI		(0.03, 0.60)
Relative Risk		0.18
95% CI		(0.05, 0.60)
Risk Difference (%)		-2.81
95% CI		(-4.54, -1.08)
p-value [1]		0.003

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	12	11
Any event	4 (33.3%)	1 (9.1%)
Odds Ratio		0.20
95% CI		(0.02, 2.16)
Relative Risk		0.27
95% CI		(0.04, 2.08)
Risk Difference (%)		-24.24
95% CI		(-55.87, 7.38)
p-value [1]		0.317

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	4 (33.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-33.33
95% CI		(-60.01, -6.66)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

Population: Safety

Table 33.79
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	3 (25.0%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-25.00
95% CI		(-49.50, -0.50)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 33.86
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	470	468
Any event	108 (23.0%)	113 (24.1%)
Odds Ratio		1.07
95% CI		(0.79, 1.44)
Relative Risk		1.05
95% CI		(0.83, 1.32)
Risk Difference (%)		1.17
95% CI		(-4.26, 6.60)
p-value [1]		0.701

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.86
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	25 (5.3%)	14 (3.0%)
Odds Ratio		0.55
95% CI		(0.28, 1.07)
Relative Risk		0.56
95% CI		(0.30, 1.07)
Risk Difference (%)		-2.33
95% CI		(-4.88, 0.22)
p-value [1]		0.101

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

Table 33.86
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	56	55
Any event	13 (23.2%)	15 (27.3%)
Odds Ratio		1.24
95% CI		(0.53, 2.93)
Relative Risk		1.17
95% CI		(0.62, 2.23)
Risk Difference (%)		4.06
95% CI		(-12.09, 20.21)
p-value [1]		0.667

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.86
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	8 (14.3%)	3 (5.5%)
Odds Ratio		0.35
95% CI		(0.09, 1.38)
Relative Risk		0.38
95% CI		(0.11, 1.36)
Risk Difference (%)		-8.83
95% CI		(-19.79, 2.12)
p-value [1]		0.203

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Protocol: 214367
Population: Safety

Table 33.87
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	470	468
Any event	25 (5.3%)	17 (3.6%)
Odds Ratio		0.67
95% CI		(0.36, 1.26)
Relative Risk		0.68
95% CI		(0.37, 1.25)
Risk Difference (%)		-1.69
95% CI		(-4.33, 0.96)
p-value [1]		0.269

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Protocol: 214367
Population: Safety

Table 33.87
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	56	55
Any event	3 (5.4%)	4 (7.3%)
Odds Ratio		1.39
95% CI		(0.30, 6.50)
Relative Risk		1.36
95% CI		(0.32, 5.79)
Risk Difference (%)		1.92
95% CI		(-7.13, 10.96)
p-value [1]		0.717

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Protocol: 214367
Population: Safety

Table 33.88
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	470	468
Any event	12 (2.6%)	6 (1.3%)
Odds Ratio		0.50
95% CI		(0.15, 1.44)
Relative Risk		0.50
95% CI		(0.19, 1.33)
Risk Difference (%)		-1.27
95% CI		(-3.02, 0.48)
p-value [1]		0.234

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.88
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	56	55
Any event	6 (10.7%)	3 (5.5%)
Odds Ratio		0.48
95% CI		(0.11, 2.03)
Relative Risk		0.51
95% CI		(0.13, 1.93)
Risk Difference (%)		-5.26
95% CI		(-15.34, 4.82)
p-value [1]		0.490

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.89
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	470	468
Any event	3 (0.6%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.89
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	56	55
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Protocol: 214367
Population: Safety

Table 33.90
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): <=70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	470	468
Any event	10 (2.1%)	6 (1.3%)
Odds Ratio		0.60
95% CI		(0.18, 1.83)
Relative Risk		0.60
95% CI		(0.22, 1.64)
Risk Difference (%)		-0.85
95% CI		(-2.50, 0.81)
p-value [1]		0.451

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.90
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Age Group (<=70, >70)

Age group (years): >70

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	56	55
Any event	6 (10.7%)	3 (5.5%)
Odds Ratio		0.48
95% CI		(0.11, 2.03)
Relative Risk		0.51
95% CI		(0.13, 1.93)
Risk Difference (%)		-5.26
95% CI		(-15.34, 4.82)
p-value [1]		0.490

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	96	98
Any event	21 (21.9%)	23 (23.5%)
Odds Ratio		1.10
95% CI		(0.56, 2.15)
Relative Risk		1.07
95% CI		(0.64, 1.81)
Risk Difference (%)		1.59
95% CI		(-10.19, 13.38)
p-value [1]		0.865

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	4 (4.2%)	4 (4.1%)
Odds Ratio		0.98
95% CI		(0.24, 4.03)
Relative Risk		0.98
95% CI		(0.25, 3.81)
Risk Difference (%)		-0.09
95% CI		(-5.68, 5.51)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	84	72
Any event	17 (20.2%)	19 (26.4%)
Odds Ratio		1.41
95% CI		(0.67, 2.98)
Relative Risk		1.30
95% CI		(0.73, 2.31)
Risk Difference (%)		6.15
95% CI		(-7.17, 19.47)
p-value [1]		0.447

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	7 (8.3%)	3 (4.2%)
Odds Ratio		0.48
95% CI		(0.12, 1.92)
Relative Risk		0.50
95% CI		(0.13, 1.86)
Risk Difference (%)		-4.17
95% CI		(-11.67, 3.33)
p-value [1]		0.343

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	14 (24.1%)	16 (25.0%)
Odds Ratio		1.05
95% CI		(0.46, 2.39)
Relative Risk		1.04
95% CI		(0.56, 1.93)
Risk Difference (%)		0.86
95% CI		(-14.43, 16.15)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	3 (5.2%)	1 (1.6%)
Odds Ratio		0.29
95% CI		(0.01, 3.78)
Relative Risk		0.30
95% CI		(0.03, 2.82)
Risk Difference (%)		-3.61
95% CI		(-10.07, 2.85)
p-value [1]		0.346

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	60	73
Any event	15 (25.0%)	17 (23.3%)
Odds Ratio		0.91
95% CI		(0.41, 2.02)
Relative Risk		0.93
95% CI		(0.51, 1.70)
Risk Difference (%)		-1.71
95% CI		(-16.34, 12.92)
p-value [1]		0.841

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	5 (8.3%)	1 (1.4%)
Odds Ratio		0.15
95% CI		(0.00, 1.44)
Relative Risk		0.16
95% CI		(0.02, 1.37)
Risk Difference (%)		-6.96
95% CI		(-14.45, 0.52)
p-value [1]		0.091

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	181	160
Any event	45 (24.9%)	36 (22.5%)
Odds Ratio		0.88
95% CI		(0.53, 1.45)
Relative Risk		0.91
95% CI		(0.62, 1.33)
Risk Difference (%)		-2.36
95% CI		(-11.39, 6.67)
p-value [1]		0.703

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.91
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	14 (7.7%)	6 (3.8%)
Odds Ratio		0.46
95% CI		(0.17, 1.24)
Relative Risk		0.48
95% CI		(0.19, 1.23)
Risk Difference (%)		-3.98
95% CI		(-8.86, 0.89)
p-value [1]		0.166

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.92
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	96	98
Any event	4 (4.2%)	4 (4.1%)
Odds Ratio		0.98
95% CI		(0.24, 4.03)
Relative Risk		0.98
95% CI		(0.25, 3.81)
Risk Difference (%)		-0.09
95% CI		(-5.68, 5.51)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.92
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	84	72
Any event	3 (3.6%)	3 (4.2%)
Odds Ratio		1.17
95% CI		(0.23, 6.00)
Relative Risk		1.17
95% CI		(0.24, 5.60)
Risk Difference (%)		0.60
95% CI		(-5.49, 6.68)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.92
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	2 (3.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-3.45 (-8.14, 1.25)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.92
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	60	73
Any event	2 (3.3%)	6 (8.2%)
Odds Ratio		2.60
95% CI		(0.50, 13.37)
Relative Risk		2.47
95% CI		(0.52, 11.77)
Risk Difference (%)		4.89
95% CI		(-2.88, 12.65)
p-value [1]		0.294

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.92
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	181	160
Any event	15 (8.3%)	6 (3.8%)
Odds Ratio		0.43
95% CI		(0.16, 1.14)
Relative Risk		0.45
95% CI		(0.18, 1.14)
Risk Difference (%)		-4.54
95% CI		(-9.52, 0.44)
p-value [1]		0.114

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Protocol: 214367
Population: Safety

Table 33.93
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	96	98
Any event	0	2 (2.0%)
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		2.04 (-0.76, 4.84)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.93
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	84	72
Any event	3 (3.6%)	1 (1.4%)
Odds Ratio		0.38
95% CI		(0.01, 4.88)
Relative Risk		0.39
95% CI		(0.04, 3.66)
Risk Difference (%)		-2.18
95% CI		(-6.98, 2.62)
p-value [1]		0.625

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.93
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	2 (3.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-3.45 (-8.14, 1.25)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.93
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	60	73
Any event	1 (1.7%)	1 (1.4%)
Odds Ratio		0.82
95% CI		(0.01, 65.40)
Relative Risk		0.82
95% CI		(0.05, 12.87)
Risk Difference (%)		-0.30
95% CI		(-4.49, 3.90)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.93
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	181	160
Any event	12 (6.6%)	3 (1.9%)
Odds Ratio		0.27
95% CI		(0.05, 1.03)
Relative Risk		0.28
95% CI		(0.08, 0.98)
Risk Difference (%)		-4.75
95% CI		(-8.94, -0.56)
p-value [1]		0.037

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Protocol: 214367
Population: Safety

Table 33.94
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	96	98
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.94
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	84	72
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.94
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.94
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	60	73
Any event	1 (1.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.94
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	181	160
Any event	2 (1.1%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.95
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	96	98
Any event	0	2 (2.0%)
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		2.04 (-0.76, 4.84)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.95
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	84	72
Any event	3 (3.6%)	1 (1.4%)
Odds Ratio		0.38
95% CI		(0.01, 4.88)
Relative Risk		0.39
95% CI		(0.04, 3.66)
Risk Difference (%)		-2.18
95% CI		(-6.98, 2.62)
p-value [1]		0.625

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.95
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	2 (3.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-3.45 (-8.14, 1.25)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.95
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	60	73
Any event	1 (1.7%)	1 (1.4%)
Odds Ratio		0.82
95% CI		(0.01, 65.40)
Relative Risk		0.82
95% CI		(0.05, 12.87)
Risk Difference (%)		-0.30
95% CI		(-4.49, 3.90)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.95
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Baseline Viral Load

Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	181	160
Any event	10 (5.5%)	3 (1.9%)
Odds Ratio		0.33
95% CI		(0.06, 1.30)
Relative Risk		0.34
95% CI		(0.10, 1.21)
Risk Difference (%)		-3.65
95% CI		(-7.59, 0.29)
p-value [1]		0.095

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.96
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	255	228
Any event	60 (23.5%)	47 (20.6%)
Odds Ratio		0.84
95% CI		(0.55, 1.30)
Relative Risk		0.88
95% CI		(0.63, 1.23)
Risk Difference (%)		-2.92
95% CI		(-10.31, 4.48)
p-value [1]		0.511

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.96
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	12 (4.7%)	9 (3.9%)
Odds Ratio		0.83
95% CI		(0.34, 2.01)
Relative Risk		0.84
95% CI		(0.36, 1.95)
Risk Difference (%)		-0.76
95% CI		(-4.38, 2.87)
p-value [1]		0.825

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.96
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	271	295
Any event	61 (22.5%)	81 (27.5%)
Odds Ratio		1.30
95% CI		(0.89, 1.91)
Relative Risk		1.22
95% CI		(0.91, 1.63)
Risk Difference (%)		4.95
95% CI		(-2.17, 12.07)
p-value [1]		0.208

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.96
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	21 (7.7%)	8 (2.7%)
Odds Ratio		0.33
95% CI		(0.14, 0.76)
Relative Risk		0.35
95% CI		(0.16, 0.78)
Risk Difference (%)		-5.04
95% CI		(-8.72, -1.35)
p-value [1]		0.008

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Protocol: 214367
Population: Safety

Table 33.97
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	255	228
Any event	18 (7.1%)	9 (3.9%)
Odds Ratio		0.54
95% CI		(0.24, 1.23)
Relative Risk		0.56
95% CI		(0.26, 1.22)
Risk Difference (%)		-3.11
95% CI		(-7.15, 0.92)
p-value [1]		0.167

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.97
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	271	295
Any event	10 (3.7%)	12 (4.1%)
Odds Ratio		1.11
95% CI		(0.47, 2.60)
Relative Risk		1.10
95% CI		(0.48, 2.51)
Risk Difference (%)		0.38
95% CI		(-2.80, 3.56)
p-value [1]		0.832

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.98
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	255	228
Any event	12 (4.7%)	5 (2.2%)
Odds Ratio		0.45
95% CI		(0.16, 1.31)
Relative Risk		0.47
95% CI		(0.17, 1.30)
Risk Difference (%)		-2.51
95% CI		(-5.73, 0.71)
p-value [1]		0.148

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.98
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	271	295
Any event	6 (2.2%)	4 (1.4%)
Odds Ratio		0.61
95% CI		(0.12, 2.59)
Relative Risk		0.61
95% CI		(0.17, 2.15)
Risk Difference (%)		-0.86
95% CI		(-3.05, 1.34)
p-value [1]		0.532

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Protocol: 214367
Population: Safety

Table 33.99
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study Excluding Events Related to COVID-19 by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	255	228
Any event	2 (0.8%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.99
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	271	295
Any event	1 (0.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.100
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Gender

Gender: Male

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	255	228
Any event	10 (3.9%)	5 (2.2%)
Odds Ratio		0.55
95% CI		(0.18, 1.63)
Relative Risk		0.56
95% CI		(0.19, 1.61)
Risk Difference (%)		-1.73
95% CI		(-4.78, 1.32)
p-value [1]		0.306

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.100
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Gender

Gender: Female

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	271	295
Any event	6 (2.2%)	4 (1.4%)
Odds Ratio		0.61
95% CI		(0.12, 2.59)
Relative Risk		0.61
95% CI		(0.17, 2.15)
Risk Difference (%)		-0.86
95% CI		(-3.05, 1.34)
p-value [1]		0.532

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.101
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	306	290
Any event	65 (21.2%)	66 (22.8%)
Odds Ratio		1.09
95% CI		(0.74, 1.61)
Relative Risk		1.07
95% CI		(0.79, 1.45)
Risk Difference (%)		1.52
95% CI		(-5.14, 8.17)
p-value [1]		0.693

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.101
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	14 (4.6%)	4 (1.4%)
Odds Ratio		0.29
95% CI		(0.07, 0.95)
Relative Risk		0.30
95% CI		(0.10, 0.91)
Risk Difference (%)		-3.20
95% CI		(-5.89, -0.50)
p-value [1]		0.030

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.101
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	151	176
Any event	35 (23.2%)	47 (26.7%)
Odds Ratio		1.21
95% CI		(0.73, 2.00)
Relative Risk		1.15
95% CI		(0.79, 1.68)
Risk Difference (%)		3.53
95% CI		(-5.86, 12.91)
p-value [1]		0.523

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.101
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	10 (6.6%)	9 (5.1%)
Odds Ratio		0.76
95% CI		(0.30, 1.92)
Relative Risk		0.77
95% CI		(0.32, 1.85)
Risk Difference (%)		-1.51
95% CI		(-6.64, 3.62)
p-value [1]		0.639

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

Table 33.101
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	69	57
Any event	21 (30.4%)	15 (26.3%)
Odds Ratio		0.82
95% CI		(0.37, 1.78)
Relative Risk		0.86
95% CI		(0.49, 1.52)
Risk Difference (%)		-4.12
95% CI		(-19.88, 11.65)
p-value [1]		0.694

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.101
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	9 (13.0%)	4 (7.0%)
Odds Ratio		0.50
95% CI		(0.15, 1.73)
Relative Risk		0.54
95% CI		(0.17, 1.66)
Risk Difference (%)		-6.03
95% CI		(-16.38, 4.32)
p-value [1]		0.381

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.102
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	306	290
Any event	14 (4.6%)	7 (2.4%)
Odds Ratio		0.52
95% CI		(0.21, 1.30)
Relative Risk		0.53
95% CI		(0.22, 1.29)
Risk Difference (%)		-2.16
95% CI		(-5.09, 0.77)
p-value [1]		0.185

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.102
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	151	176
Any event	6 (4.0%)	10 (5.7%)
Odds Ratio		1.46
95% CI		(0.52, 4.10)
Relative Risk		1.43
95% CI		(0.53, 3.84)
Risk Difference (%)		1.71
95% CI		(-2.92, 6.33)
p-value [1]		0.610

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.102
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	69	57
Any event	8 (11.6%)	4 (7.0%)
Odds Ratio		0.58
95% CI		(0.16, 2.02)
Relative Risk		0.61
95% CI		(0.19, 1.91)
Risk Difference (%)		-4.58
95% CI		(-14.63, 5.48)
p-value [1]		0.545

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.103
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	306	290
Any event	9 (2.9%)	2 (0.7%)
Odds Ratio		0.23
95% CI		(0.02, 1.12)
Relative Risk		0.23
95% CI		(0.05, 1.08)
Risk Difference (%)		-2.25
95% CI		(-4.37, -0.13)
p-value [1]		0.065

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.103
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	151	176
Any event	6 (4.0%)	4 (2.3%)
Odds Ratio		0.56
95% CI		(0.16, 2.03)
Relative Risk		0.57
95% CI		(0.16, 1.99)
Risk Difference (%)		-1.70
95% CI		(-5.52, 2.11)
p-value [1]		0.523

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.103
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	69	57
Any event	3 (4.3%)	3 (5.3%)
Odds Ratio		1.22
95% CI		(0.24, 6.30)
Relative Risk		1.21
95% CI		(0.25, 5.77)
Risk Difference (%)		0.92
95% CI		(-6.62, 8.45)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Protocol: 214367
Population: Safety

Table 33.104
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	306	290
Any event	1 (0.3%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.104
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	151	176
Any event	1 (0.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.104
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	69	57
Any event	1 (1.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

Population: Safety

Table 33.105
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: <=1

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	306	290
Any event	9 (2.9%)	2 (0.7%)
Odds Ratio		0.23
95% CI		(0.02, 1.12)
Relative Risk		0.23
95% CI		(0.05, 1.08)
Risk Difference (%)		-2.25
95% CI		(-4.37, -0.13)
p-value [1]		0.065

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.105
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: 2

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	151	176
Any event	5 (3.3%)	4 (2.3%)
Odds Ratio		0.68
95% CI		(0.18, 2.58)
Relative Risk		0.69
95% CI		(0.19, 2.51)
Risk Difference (%)		-1.04
95% CI		(-4.64, 2.57)
p-value [1]		0.738

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.105
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Number of Risk Factors

Number of risk factors: >=3

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	69	57
Any event	2 (2.9%)	3 (5.3%)
Odds Ratio		1.86
95% CI		(0.30, 11.54)
Relative Risk		1.82
95% CI		(0.31, 10.50)
Risk Difference (%)		2.36
95% CI		(-4.65, 9.38)
p-value [1]		0.658

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.106
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	237	240
Any event	51 (21.5%)	65 (27.1%)
Odds Ratio		1.35
95% CI		(0.89, 2.06)
Relative Risk		1.26
95% CI		(0.91, 1.73)
Risk Difference (%)		5.56
95% CI		(-2.12, 13.24)
p-value [1]		0.167

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.106
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	14 (5.9%)	8 (3.3%)
Odds Ratio		0.55
95% CI		(0.23, 1.33)
Relative Risk		0.56
95% CI		(0.24, 1.32)
Risk Difference (%)		-2.57
95% CI		(-6.34, 1.19)
p-value [1]		0.198

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.106
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	212	219
Any event	48 (22.6%)	46 (21.0%)
Odds Ratio		0.91
95% CI		(0.58, 1.44)
Relative Risk		0.93
95% CI		(0.65, 1.33)
Risk Difference (%)		-1.64
95% CI		(-9.44, 6.16)
p-value [1]		0.727

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.106
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	11 (5.2%)	5 (2.3%)
Odds Ratio		0.43
95% CI		(0.15, 1.25)
Relative Risk		0.44
95% CI		(0.16, 1.25)
Risk Difference (%)		-2.91
95% CI		(-6.49, 0.68)
p-value [1]		0.131

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.107
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	237	240
Any event	11 (4.6%)	5 (2.1%)
Odds Ratio		0.44
95% CI		(0.15, 1.28)
Relative Risk		0.45
95% CI		(0.16, 1.27)
Risk Difference (%)		-2.56
95% CI		(-5.79, 0.67)
p-value [1]		0.135

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.107
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	212	219
Any event	11 (5.2%)	14 (6.4%)
Odds Ratio		1.25
95% CI		(0.55, 2.81)
Relative Risk		1.23
95% CI		(0.57, 2.65)
Risk Difference (%)		1.20
95% CI		(-3.20, 5.61)
p-value [1]		0.683

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Protocol: 214367
Population: Safety

Table 33.108
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	237	240
Any event	6 (2.5%)	4 (1.7%)
Odds Ratio		0.65
95% CI		(0.13, 2.79)
Relative Risk		0.66
95% CI		(0.19, 2.30)
Risk Difference (%)		-0.86
95% CI		(-3.44, 1.71)
p-value [1]		0.543

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.108
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	212	219
Any event	5 (2.4%)	4 (1.8%)
Odds Ratio		0.77
95% CI		(0.15, 3.64)
Relative Risk		0.77
95% CI		(0.21, 2.84)
Risk Difference (%)		-0.53
95% CI		(-3.24, 2.17)
p-value [1]		0.748

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Protocol: 214367
Population: Safety

Table 33.109
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	237	240
Any event	2 (0.8%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.109
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	212	219
Any event	1 (0.5%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.110
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: <2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	237	240
Any event	5 (2.1%)	4 (1.7%)
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.110
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Patient Reported Symptom Severity

Patient Reported Symptom Severity: >=2 moderate/higher intensity

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	212	219
Any event	4 (1.9%)	4 (1.8%)
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.111
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	15	13
Any event	7 (46.7%)	6 (46.2%)
Odds Ratio		0.98
95% CI		(0.22, 4.34)
Relative Risk		0.99
95% CI		(0.45, 2.20)
Risk Difference (%)		-0.51
95% CI		(-37.55, 36.52)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.111
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	3 (20.0%)	1 (7.7%)
Odds Ratio		0.33
95% CI		(0.03, 3.68)
Relative Risk		0.38
95% CI		(0.05, 3.26)
Risk Difference (%)		-12.31
95% CI		(-37.20, 12.58)
p-value [1]		0.600

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.111
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	499	499
Any event	108 (21.6%)	117 (23.4%)
Odds Ratio		1.11
95% CI		(0.82, 1.49)
Relative Risk		1.08
95% CI		(0.86, 1.36)
Risk Difference (%)		1.80
95% CI		(-3.38, 6.99)
p-value [1]		0.545

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.111
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	27 (5.4%)	16 (3.2%)
Odds Ratio		0.58
95% CI		(0.31, 1.09)
Relative Risk		0.59
95% CI		(0.32, 1.09)
Risk Difference (%)		-2.20
95% CI		(-4.72, 0.31)
p-value [1]		0.119

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.111
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	12	11
Any event	6 (50.0%)	5 (45.5%)
Odds Ratio		0.83
95% CI		(0.16, 4.30)
Relative Risk		0.91
95% CI		(0.38, 2.15)
Risk Difference (%)		-4.55
95% CI		(-45.36, 36.27)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.111
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	3 (25.0%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-25.00
95% CI		(-49.50, -0.50)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Protocol: 214367
Population: Safety

Table 33.112
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	15	13
Any event	1 (6.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-6.67 (-19.29, 5.96)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.112
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	499	499
Any event	25 (5.0%)	20 (4.0%)
Odds Ratio		0.79
95% CI		(0.43, 1.44)
Relative Risk		0.80
95% CI		(0.45, 1.42)
Risk Difference (%)		-1.00
95% CI		(-3.58, 1.57)
p-value [1]		0.543

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.112
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
Excluding Events Related to COVID-19 by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	12	11
Any event	2 (16.7%)	1 (9.1%)
Odds Ratio		0.50
95% CI		(0.04, 6.44)
Relative Risk		0.55
95% CI		(0.06, 5.21)
Risk Difference (%)		-7.58
95% CI		(-34.65, 19.50)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.113
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	15	13
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.113
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	499	499
Any event	14 (2.8%)	9 (1.8%)
Odds Ratio		0.64
95% CI		(0.24, 1.60)
Relative Risk		0.64
95% CI		(0.28, 1.47)
Risk Difference (%)		-1.00
95% CI		(-2.86, 0.86)
p-value [1]		0.400

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.113
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	12	11
Any event	4 (33.3%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-33.33 (-60.01, -6.66)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.114
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	15	13
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.114
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	499	499
Any event	3 (0.6%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 33.114
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	12	11
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Protocol: 214367
Population: Safety

Table 33.115
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Region

Region: Europe

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	15	13
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.115
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Region

Region: North America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	499	499
Any event	12 (2.4%)	9 (1.8%)
Odds Ratio		0.75
95% CI		(0.27, 1.95)
Relative Risk		0.75
95% CI		(0.32, 1.76)
Risk Difference (%)		-0.60
95% CI		(-2.38, 1.18)
p-value [1]		0.661

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Table 33.115
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Region

Region: South America

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	12	11
Any event	4 (33.3%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-33.33 (-60.01, -6.66)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

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Population: Safety Data as of 27APR2021

Table 23.64
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Adverse Events

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.517
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.488
	Gender (Female, Male)	0.054
	Number of risk factors (<=1, 2, >=3)	0.868
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.117
	Region (North America, Europe, South America)	>0.999
Infections and infestations Any event	Age group (<=70, >70 years old)	0.725
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.159
	Gender (Female, Male)	0.152
	Number of risk factors (<=1, 2, >=3)	0.119
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.181
	Region (North America, Europe, South America)	0.080
Infections and infestations COVID-19 pneumonia	Age group (<=70, >70 years old)	0.199
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.094
	Gender (Female, Male)	0.816
	Number of risk factors (<=1, 2, >=3)	0.079
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.816
	Region (North America, Europe, South America)	0.350

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Table 23.65
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Adverse Events

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.465
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.188
	Gender (Female, Male)	0.856
	Number of risk factors (<=1, 2, >=3)	0.068
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.873
	Region (North America, Europe, South America)	0.121
Infections and infestations Any event	Age group (<=70, >70 years old)	0.079
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.074
	Gender (Female, Male)	0.716
	Number of risk factors (<=1, 2, >=3)	0.578
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.515
	Region (North America, Europe, South America)	0.322

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

Table 23.65
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Adverse Events

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Infections and infestations		
COVID-19 pneumonia	Age group (<=70, >70 years old)	0.065
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	NC
	Gender (Female, Male)	0.589
	Number of risk factors (<=1, 2, >=3)	0.103
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.447
	Region (North America, Europe, South America)	0.483

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

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Population: Safety Data as of 27APR2021

Table 23.66
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Adverse Events Leading to Withdrawal from Study

No data to report

PPD

Protocol: 214367
Population: Safety Data as of 27APR2021

Table 23.67
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity

Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.993
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.063
	Gender (Female, Male)	0.675
	Number of risk factors (<=1, 2, >=3)	0.513
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.617
	Region (North America, Europe, South America)	0.499

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.68
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Cardiac Events of Special Interest

No data to report

Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

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Population: Safety Data as of 27APR2021

Table 23.69
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Infusion-Related Reactions including Hypersensitivity

No data to report

Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 23.70
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Cardiac Events of Special Interest

No data to report

Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 23.71
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Fatal Serious Adverse Events

No data to report

Table 23.72
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Non-Fatal Serious Adverse Events

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.310
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.223
	Gender (Female, Male)	0.809
	Number of risk factors (<=1, 2, >=3)	0.042
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.762
	Region (North America, Europe, South America)	0.097
Infections and infestations Any event	Age group (<=70, >70 years old)	0.036
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.083
	Gender (Female, Male)	0.675
	Number of risk factors (<=1, 2, >=3)	0.499
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.417
	Region (North America, Europe, South America)	0.273

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

Table 23.72
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Non-Fatal Serious Adverse Events

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Infections and infestations		
COVID-19 pneumonia	Age group (<=70, >70 years old)	0.017
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	NC
	Gender (Female, Male)	0.604
	Number of risk factors (<=1, 2, >=3)	0.106
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.435
	Region (North America, Europe, South America)	0.442

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

Protocol: 214367
Population: Safety Data as of 27APR2021

Table 23.80
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.231
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.264
	Gender (Female, Male)	0.352
	Number of risk factors (<=1, 2, >=3)	0.499
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.166
	Region (North America, Europe, South America)	0.511
Infections and infestations Any event	Age group (<=70, >70 years old)	0.018
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	NC
	Gender (Female, Male)	0.847
	Number of risk factors (<=1, 2, >=3)	0.125
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.830
	Region (North America, Europe, South America)	0.397

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

Table 23.80
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Infections and infestations		
COVID-19 pneumonia	Age group (<=70, >70 years old)	0.059
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	NC
	Gender (Female, Male)	0.637
	Number of risk factors (<=1, 2, >=3)	0.133
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.456
	Region (North America, Europe, South America)	0.583

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

Protocol: 214367
Population: Safety Data as of 27APR2021

Table 23.116
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.678
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.908
	Gender (Female, Male)	0.027
	Number of risk factors (<=1, 2, >=3)	0.846
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.271
	Region (North America, Europe, South America)	0.947
Infections and infestations Any event	Age group (<=70, >70 years old)	0.914
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.314
	Gender (Female, Male)	0.056
	Number of risk factors (<=1, 2, >=3)	0.374
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.207
	Region (North America, Europe, South America)	0.149

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Protocol: 214367
Population: Safety Data as of 27APR2021

Table 23.117
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 Excluding Events Related to COVID-19

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.247
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.380
	Gender (Female, Male)	0.181
	Number of risk factors (<=1, 2, >=3)	0.350
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.189
	Region (North America, Europe, South America)	0.635

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Protocol: 214367
Population: Safety Data as of 27APR2021

Table 23.118
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.755
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.168
	Gender (Female, Male)	0.752
	Number of risk factors (<=1, 2, >=3)	0.328
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.507
	Region (North America, Europe, South America)	NC

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

Table 23.119
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Adverse Events Leading to Withdrawal from Study Excluding Events Related to COVID-19

No data to report

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Population: Safety Data as of 27APR2021

Table 23.120
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.658
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.177
	Gender (Female, Male)	0.847
	Number of risk factors (<=1, 2, >=3)	0.225
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.638
	Region (North America, Europe, South America)	NC

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

Protocol: 214367
Population: Safety

Table 33.64
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Adverse Events

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.706
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.501
	Gender (Female, Male)	0.298
	Number of risk factors (<=1, 2, >=3)	0.759
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.126
	Region (North America, Europe, South America)	0.979
Infections and infestations Any event	Age group (<=70, >70 years old)	0.882
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.454
	Gender (Female, Male)	0.301
	Number of risk factors (<=1, 2, >=3)	0.123
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.588
	Region (North America, Europe, South America)	0.147
Infections and infestations COVID-19 pneumonia	Age group (<=70, >70 years old)	0.200
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.094
	Gender (Female, Male)	0.816
	Number of risk factors (<=1, 2, >=3)	0.079
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.827
	Region (North America, Europe, South America)	0.351

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Table 33.65
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Adverse Events

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.375
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.166
	Gender (Female, Male)	0.896
	Number of risk factors (<=1, 2, >=3)	0.059
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.728
	Region (North America, Europe, South America)	0.145
Infections and infestations Any event	Age group (<=70, >70 years old)	0.079
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.074
	Gender (Female, Male)	0.716
	Number of risk factors (<=1, 2, >=3)	0.578
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.525
	Region (North America, Europe, South America)	0.322

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

Population: Safety

Table 33.65
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Adverse Events

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Infections and infestations		
COVID-19 pneumonia	Age group (<=70, >70 years old)	0.066
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	NC
	Gender (Female, Male)	0.589
	Number of risk factors (<=1, 2, >=3)	0.103
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.454
	Region (North America, Europe, South America)	0.484

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

Table 33.66
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Adverse Events Leading to Withdrawal from Study

No data to report

PPD

Protocol: 214367
Population: Safety

Table 33.67
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity

Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.913
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.066
	Gender (Female, Male)	0.534
	Number of risk factors (<=1, 2, >=3)	0.408
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.490
	Region (North America, Europe, South America)	0.461

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 33.68
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Cardiac Events of Special Interest

No data to report

Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Protocol: 214367
Population: Safety

Table 33.69
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Infusion-Related Reactions including Hypersensitivity

No data to report

Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 33.70
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Cardiac Events of Special Interest

No data to report

Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 33.71
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Fatal Serious Adverse Events

No data to report

PPD

Table 33.72
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Non-Fatal Serious Adverse Events

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.262
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.205
	Gender (Female, Male)	0.793
	Number of risk factors (<=1, 2, >=3)	0.038
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.690
	Region (North America, Europe, South America)	0.113
Infections and infestations Any event	Age group (<=70, >70 years old)	0.036
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.083
	Gender (Female, Male)	0.675
	Number of risk factors (<=1, 2, >=3)	0.499
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.426
	Region (North America, Europe, South America)	0.274

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

Table 33.72
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Non-Fatal Serious Adverse Events

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Infections and infestations		
COVID-19 pneumonia	Age group (<=70, >70 years old)	0.017
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	NC
	Gender (Female, Male)	0.604
	Number of risk factors (<=1, 2, >=3)	0.107
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.442
	Region (North America, Europe, South America)	0.443

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

Population: Safety

Table 33.80
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.424
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.123
	Gender (Female, Male)	0.568
	Number of risk factors (<=1, 2, >=3)	0.336
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.177
	Region (North America, Europe, South America)	0.399
Infections and infestations Any event	Age group (<=70, >70 years old)	0.048
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	NC
	Gender (Female, Male)	0.535
	Number of risk factors (<=1, 2, >=3)	0.085
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.856
	Region (North America, Europe, South America)	0.322

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

Table 33.80
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Infections and infestations		
COVID-19 pneumonia	Age group (<=70, >70 years old)	0.060
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	NC
	Gender (Female, Male)	0.637
	Number of risk factors (<=1, 2, >=3)	0.133
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.464
	Region (North America, Europe, South America)	0.583

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

Protocol: 214367
Population: Safety

Table 33.116
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.782
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.922
	Gender (Female, Male)	0.199
	Number of risk factors (<=1, 2, >=3)	0.776
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.273
	Region (North America, Europe, South America)	0.951
Infections and infestations Any event	Age group (<=70, >70 years old)	0.602
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.670
	Gender (Female, Male)	0.148
	Number of risk factors (<=1, 2, >=3)	0.418
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.721
	Region (North America, Europe, South America)	0.276

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Table 33.117
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 Excluding Events Related to COVID-19

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.403
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.166
	Gender (Female, Male)	0.248
	Number of risk factors (<=1, 2, >=3)	0.311
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.126
	Region (North America, Europe, South America)	0.573

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Population: Safety

Table 33.118
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.988
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.138
	Gender (Female, Male)	0.745
	Number of risk factors (<=1, 2, >=3)	0.322
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.862
	Region (North America, Europe, South America)	NC

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

Table 33.119
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Adverse Events Leading to Withdrawal from Study Excluding Events Related to COVID-19

No data to report

Table 33.120
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Age group (<=70, >70 years old)	0.847
	Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.158
	Gender (Female, Male)	0.915
	Number of risk factors (<=1, 2, >=3)	0.197
	Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.835
	Region (North America, Europe, South America)	NC

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

Table 213.10
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Adverse Events

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.331
Infections and infestations Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.358
Infections and infestations COVID-19 pneumonia	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.084

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

Population: Safety

Table 213.11
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Adverse Events

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.105
Infections and infestations Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.069
Infections and infestations COVID-19 pneumonia	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	NC

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

Table 213.12
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Adverse Events Leading to Withdrawal from Study

No data to report

PPD

Population: Safety

Table 213.13
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity

Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.067

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 213.14
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Cardiac Events of Special Interest

No data to report

Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

PPD

Protocol: 214367
Population: Safety

Table 213.15
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Infusion-Related Reactions including Hypersensitivity

No data to report

Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 213.16
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Cardiac Events of Special Interest

No data to report

Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.

Table 213.17
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Fatal Serious Adverse Events

No data to report

PPD

Population: Safety

Table 213.18
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Non-Fatal Serious Adverse Events

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.140
Infections and infestations Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.077
Infections and infestations COVID-19 pneumonia	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	NC

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

Table 213.20
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.060
Infections and infestations Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	NC
Infections and infestations COVID-19 pneumonia	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	NC

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
NC = Not calculable.

PPD

Population: Safety

Table 213.26
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.822
Infections and infestations Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.638

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Population: Safety

Table 213.27
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 Excluding Events Related to COVID-19

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.112

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Population: Safety

Table 213.28
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.122

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Table 213.29
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Adverse Events Leading to Withdrawal from Study Excluding Events Related to COVID-19

No data to report

PPD

Protocol: 214367 Page 1 of 1
Population: Safety

Table 213.30
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.149

[1] Interaction p-values obtained from separate Poisson regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Protocol: 214367
Population: Week 24 Virology

Table 211.1
Summary of Demographic Characteristics

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)	Total (N=777)
Sex			
n	394	383	777
F	197 (50%)	201 (52%)	398 (51%)
M	197 (50%)	182 (48%)	379 (49%)
Age (YEARS) [1]			
n	394	383	777
Mean	53.2	51.8	52.5
SD	15.30	15.05	15.19
Median	55.0	53.0	54.0
Min.	17	18	17
Max.	88	94	94
Age Group (YEARS) [1]			
n	394	383	777
<=18	4 (1%)	1 (<1%)	5 (<1%)
19 - 64	302 (77%)	307 (80%)	609 (78%)
>=65	88 (22%)	75 (20%)	163 (21%)
Age Group 2 (YEARS) [1]			
n	394	383	777
<55	192 (49%)	203 (53%)	395 (51%)
55 - 64	114 (29%)	105 (27%)	219 (28%)
65 - 74	55 (14%)	52 (14%)	107 (14%)
75 - 84	26 (7%)	19 (5%)	45 (6%)
>=85	7 (2%)	4 (1%)	11 (1%)

[1] Age is imputed from year of birth. The calculation uses 30 June as the day and month and calculates age relative to Screening date.
Note: Percentages are calculated from the displayed n counts.
PPD

Protocol: 214367
Population: Week 24 Virology

Table 211.1
Summary of Demographic Characteristics

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)	Total (N=777)
Ethnicity			
n	394	383	777
HISPANIC OR LATINO	235 (60%)	228 (60%)	463 (60%)
NOT HISPANIC OR LATINO	159 (40%)	155 (40%)	314 (40%)
High Level Race			
n	393	382	775
AMERICAN INDIAN OR ALASKA NATIVE	2 (<1%)	0	2 (<1%)
ASIAN	21 (5%)	23 (6%)	44 (6%)
BLACK OR AFRICAN AMERICAN	32 (8%)	28 (7%)	60 (8%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0
WHITE	338 (86%)	330 (86%)	668 (86%)
MIXED RACE	0	1 (<1%)	1 (<1%)
Race Detail			
n	393	382	775
AMERICAN INDIAN OR ALASKA NATIVE	2 (<1%)	0	2 (<1%)
ASIAN - CENTRAL/SOUTH ASIAN HERITAGE	11 (3%)	13 (3%)	24 (3%)
ASIAN - EAST ASIAN HERITAGE	7 (2%)	3 (<1%)	10 (1%)
ASIAN - JAPANESE HERITAGE	0	0	0
ASIAN - SOUTH EAST ASIAN HERITAGE	3 (<1%)	6 (2%)	9 (1%)
BLACK OR AFRICAN AMERICAN	32 (8%)	28 (7%)	60 (8%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0
WHITE - ARABIC/NORTH AFRICAN HERITAGE	8 (2%)	10 (3%)	18 (2%)
WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE	330 (84%)	317 (83%)	647 (83%)
MIXED ASIAN RACE	0	1 (<1%)	1 (<1%)
MIXED WHITE RACE	0	3 (<1%)	3 (<1%)
MIXED RACE	0	1 (<1%)	1 (<1%)

[1] Age is imputed from year of birth. The calculation uses 30 June as the day and month and calculates age relative to Screening date.
Note: Percentages are calculated from the displayed n counts.
PPD

Population: Week 24 Virology

Table 211.1
Summary of Demographic Characteristics

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)	Total (N=777)
Height (cm)			
n	394	383	777
Mean	167.4	166.9	167.2
SD	9.80	10.32	10.06
Median	167.0	166.0	167.0
Min.	145	143	143
Max.	198	200	200
Weight (kg)			
n	394	383	777
Mean	90.06	91.38	90.71
SD	19.888	22.555	21.241
Median	88.80	89.00	89.00
Min.	41.0	49.0	41.0
Max.	174.0	183.0	183.0
BMI (kg/m^2)			
n	394	383	777
Mean	32.08	32.69	32.38
SD	6.205	7.021	6.622
Median	31.81	32.38	32.02
Min.	17.7	17.0	17.0
Max.	54.9	71.1	71.1
BMI Category (kg/m^2)			
n	394	383	777
<=30	141 (36%)	134 (35%)	275 (35%)
>30 - <=35	135 (34%)	122 (32%)	257 (33%)
>35	118 (30%)	127 (33%)	245 (32%)

[1] Age is imputed from year of birth. The calculation uses 30 June as the day and month and calculates age relative to Screening date.
Note: Percentages are calculated from the displayed n counts.
PPD

Protocol: 214367
Population: Week 24 Virology

Table 211.2
Summary of Disease Characteristics at Baseline

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)	Total (N=777)
Positive local SARS-CoV-2 test result [1]			
Yes	394 (100%)	383 (100%)	777 (100%)
Missing	0	0	0
Specimen type			
n	394	383	777
NASAL CAVITY SWAB	87 (22%)	104 (27%)	191 (25%)
NASOPHARYNGEAL SWAB	294 (75%)	261 (68%)	555 (71%)
OROPHARYNGEAL SWAB	6 (2%)	11 (3%)	17 (2%)
SALIVA	7 (2%)	5 (1%)	12 (2%)
OTHER	0	2 (<1%)	2 (<1%)
Method of diagnosis			
n	394	383	777
REVERSE TRANSCRIPTASE PCR	326 (83%)	311 (81%)	637 (82%)
ANTIGEN	68 (17%)	72 (19%)	140 (18%)
OTHER	0	0	0

Note: Subjects may occur more than once in the list of risk factors and the list of symptoms present.
[1] Local SARS-CoV-2 diagnostic test results for study inclusion.
[2] Medical conditions present as risk factors at Screening. Obesity risk was updated under protocol amendment 1; BMI was amended from >30 to >35. Subjects with BMI>30 are included here, regardless of the protocol version under which they were screened.
[3] Central Nasopharyngeal Swab. Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value. Percentages are based on the number of non-missing results.

PPD

Table 211.2
Summary of Disease Characteristics at Baseline

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)	Total (N=777)
Conditions as risk factor for COVID-19 progression [2]			
Any condition	392 (>99%)	383 (100%)	775 (>99%)
Obesity (BMI >30 kg/m^2)	253 (64%)	249 (65%)	502 (65%)
Age >= 55 (YEARS)	202 (51%)	180 (47%)	382 (49%)
Diabetes requiring medication	87 (22%)	88 (23%)	175 (23%)
Moderate to severe asthma	51 (13%)	58 (15%)	109 (14%)
COPD	23 (6%)	18 (5%)	41 (5%)
Chronic kidney disease (eGFR <60 by MDRD)	6 (2%)	3 (<1%)	9 (1%)
Congestive Heart failure (NYHA class II or more)	2 (<1%)	4 (1%)	6 (<1%)
Number of conditions met			
0	2 (<1%)	0	2 (<1%)
1	223 (57%)	213 (56%)	436 (56%)
2	117 (30%)	129 (34%)	246 (32%)
3	41 (10%)	36 (9%)	77 (10%)
>3	11 (3%)	5 (1%)	16 (2%)

Note: Subjects may occur more than once in the list of risk factors and the list of symptoms present.
[1] Local SARS-CoV-2 diagnostic test results for study inclusion.
[2] Medical conditions present as risk factors at Screening. Obesity risk was updated under protocol amendment 1; BMI was amended from >30 to >35. Subjects with BMI>30 are included here, regardless of the protocol version under which they were screened.
[3] Central Nasopharyngeal Swab. Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value. Percentages are based on the number of non-missing results.

PPD

Table 211.2
Summary of Disease Characteristics at Baseline

	Placebo (N=394)		Sotrovimab (500mg IV) (N=383)		Total (N=777)	
Symptoms present						
Cough	328	(83%)	307	(80%)	635	(82%)
Muscle aches (myalgia)	279	(71%)	278	(73%)	557	(72%)
Headache	278	(71%)	270	(70%)	548	(71%)
Fatigue	249	(63%)	232	(61%)	481	(62%)
Malaise	233	(59%)	230	(60%)	463	(60%)
Fever	212	(54%)	204	(53%)	416	(54%)
Sore throat	210	(53%)	202	(53%)	412	(53%)
Joint pain (arthralgia)	206	(52%)	197	(51%)	403	(52%)
Chills	195	(49%)	202	(53%)	397	(51%)
Loss of taste	200	(51%)	197	(51%)	397	(51%)
Loss of smell	196	(50%)	199	(52%)	395	(51%)
Shortness of breath	152	(39%)	159	(42%)	311	(40%)
Diarrhea	133	(34%)	115	(30%)	248	(32%)
Nausea	103	(26%)	113	(30%)	216	(28%)
Vomiting	47	(12%)	38	(10%)	85	(11%)
Symptom duration						
n	394		383		777	
<=3 days	231	(59%)	228	(60%)	459	(59%)
4-5 days	163	(41%)	155	(40%)	318	(41%)
>5 days	0		0		0	

Note: Subjects may occur more than once in the list of risk factors and the list of symptoms present.
[1] Local SARS-CoV-2 diagnostic test results for study inclusion.
[2] Medical conditions present as risk factors at Screening. Obesity risk was updated under protocol amendment 1; BMI was amended from >30 to >35. Subjects with BMI>30 are included here, regardless of the protocol version under which they were screened.
[3] Central Nasopharyngeal Swab. Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value. Percentages are based on the number of non-missing results.

PPD

Protocol: 214367
Population: Week 24 Virology

Table 211.2
Summary of Disease Characteristics at Baseline

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)	Total (N=777)
Week 24 Baseline SARS-CoV-2 viral load (log10 copies/mL) in nasal secretions [3]			
n	394	383	777
Mean	6.639	6.538	6.589
SD	1.6733	1.6452	1.6593
Median	6.830	6.596	6.715
Min.	3.367	3.373	3.367
Max.	10.040	10.009	10.040
Not detectable	0	0	0
<2228 copies/mL (<LLQ)	0	0	0
<=log 10^5	87 (22%)	76 (20%)	163 (21%)
>log 10^5 - <=log 10^6	58 (15%)	64 (17%)	122 (16%)
>log 10^6 - <=log 10^7	62 (16%)	77 (20%)	139 (18%)
>log 10^7	187 (47%)	166 (43%)	353 (45%)

Note: Subjects may occur more than once in the list of risk factors and the list of symptoms present.
[1] Local SARS-CoV-2 diagnostic test results for study inclusion.
[2] Medical conditions present as risk factors at Screening. Obesity risk was updated under protocol amendment 1; BMI was amended from >30 to >35. Subjects with BMI>30 are included here, regardless of the protocol version under which they were screened.
[3] Central Nasopharyngeal Swab. Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value. Percentages are based on the number of non-missing results.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 212.1
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19
(Hospitalization > 24 hours or Death) through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	0	1 (<1%)
Hospitalized > 24 hours	0	1 (<1%)
Death	0	0
Alive and not hospitalized > 24 hours	97 (100%)	100 (>99%)
Missing [1]	0	0
Sotrovimab (500mg IV) vs. Placebo:		
Risk Difference (%) [3]		0.99
95% C.I.		(-0.94, 2.92)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Population: Intent-to-Treat

Table 212.1
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	3 (3%)	2 (3%)
Hospitalized > 24 hours	3 (3%)	2 (3%)
Death	0	0
Alive and not hospitalized > 24 hours	84 (97%)	74 (97%)
Missing [1]	0	0
Sotrovimab (500mg IV) vs. Placebo:		
Odds Ratio [2]		0.74
95% C.I.		(0.12, 4.58)
p-value		0.747
Risk Difference (%) [3]		-0.82
95% C.I.		(-6.08, 4.44)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Population: Intent-to-Treat

Table 212.1
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	5 (9%)	1 (2%)
Hospitalized > 24 hours	5 (9%)	1 (2%)
Death	0	0
Alive and not hospitalized > 24 hours	53 (91%)	62 (97%)
Missing [1]	0	1 (2%)
Sotrovimab (500mg IV) vs. Placebo:		
Odds Ratio [2]		0.34
95% C.I.		(0.06, 1.85)
p-value		0.214
Risk Difference (%) [3]		-5.50
95% C.I.		(-13.88, 2.89)
p-value		0.256

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 212.1
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19
(Hospitalization > 24 hours or Death) through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	62	77
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	3 (5%)	0
Hospitalized > 24 hours	3 (5%)	0
Death	0	0
Alive and not hospitalized > 24 hours	58 (94%)	76 (99%)
Missing [1]	1 (2%)	1 (1%)
Sotrovimab (500mg IV) vs. Placebo:		
Odds Ratio [2]		0.19
95% C.I.		(0.02, 1.72)
p-value		0.140
Risk Difference (%) [3]		-5.15
95% C.I.		(-11.77, 1.46)
p-value		0.173

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Population: Intent-to-Treat

Table 212.1
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19
(Hospitalization > 24 hours or Death) through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
Progression Status, n (%)		
Hospitalized > 24 hours and/or Death	18 (10%)	2 (1%)
Hospitalized > 24 hours	17 (9%)	2 (1%)
Death	2 (1%)	0
Alive and not hospitalized > 24 hours	166 (89%)	164 (99%)
Missing [1]	3 (2%)	0
Sotrovimab (500mg IV) vs. Placebo:		
Odds Ratio [2]		0.10
95% C.I.		(0.02, 0.43)
p-value		0.003
Risk Difference (%) [3]		-10.03
95% C.I.		(-14.85, -5.21)
p-value		<0.001

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 212.2
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19
(Hospitalization or ER Visit or Death) through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	0	1 (<1%)
Hospitalized	0	1 (<1%)
ER visit	0	0
Death	0	0
Alive and not hospitalized and no ER visit	97 (100%)	100 (>99%)
Missing [1]	0	0
Sotrovimab (500mg IV) vs. Placebo:		
Risk Difference (%) [3]		0.99
95% C.I.		(-0.94, 2.92)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 212.2
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19
(Hospitalization or ER Visit or Death) through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	3 (3%)	3 (4%)
Hospitalized	3 (3%)	2 (3%)
ER visit	0	1 (1%)
Death	0	0
Alive and not hospitalized and no ER visit	84 (97%)	73 (96%)
Missing [1]	0	0
Sotrovimab (500mg IV) vs. Placebo:		
Odds Ratio [2]		1.11
95% C.I.		(0.22, 5.70)
p-value		0.898
Risk Difference (%) [3]		0.50
95% C.I.		(-5.32, 6.32)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.
PPD

Protocol: 214367
Population: Intent-to-Treat

Table 212.2
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	6 (10%)	1 (2%)
Hospitalized	5 (9%)	1 (2%)
ER visit	1 (2%)	0
Death	0	0
Alive and not hospitalized and no ER visit	52 (90%)	62 (97%)
Missing [1]	0	1 (2%)
Sotrovimab (500mg IV) vs. Placebo:		
Odds Ratio [2]		0.29
95% C.I.		(0.06, 1.49)
p-value		0.139
Risk Difference (%) [3]		-7.22
95% C.I.		(-16.14, 1.70)
p-value		0.149

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.
PPD

Population: Intent-to-Treat

Table 212.2
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER Visit or Death) through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	62	77
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	3 (5%)	4 (5%)
Hospitalized	3 (5%)	1 (1%)
ER visit	1 (2%)	3 (4%)
Death	0	0
Alive and not hospitalized and no ER visit	58 (94%)	72 (94%)
Missing [1]	1 (2%)	1 (1%)
Sotrovimab (500mg IV) vs. Placebo:		
Odds Ratio [2]		0.99
95% C.I.		(0.25, 3.88)
p-value		0.992
Risk Difference (%) [3]		0.04
95% C.I.		(-8.19, 8.27)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 212.2
Summary and Analysis of Proportion of Subjects Who Have Progression of COVID-19
(Hospitalization or ER Visit or Death) through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
Progression Status, n (%)		
Hospitalized, ER visit and/or Death	26 (14%)	4 (2%)
Hospitalized	17 (9%)	2 (1%)
ER visit	10 (5%)	2 (1%)
Death	2 (1%)	0
Alive and not hospitalized and no ER visit	158 (84%)	162 (98%)
Missing [1]	3 (2%)	0
Sotrovimab (500mg IV) vs. Placebo:		
Odds Ratio [2]		0.14
95% C.I.		(0.05, 0.40)
p-value		<0.001
Risk Difference (%) [3]		-13.10
95% C.I.		(-18.79, -7.41)
p-value		<0.001

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered as progressions.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in each subcategory of progression experienced up to the time point in question and so may be included in more than one category.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 212.3
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
Progression Status, n (%)		
No Progression [1]	97 (100%)	99 (98%)
Any Progression	0	2 (2%)
Category 2: Low flow nasal cannulae/face mask	0	2 (2%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	0	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	0	0
Death	0	0
Missing [2]	0	0
Sotrovimab (500mg IV) vs. Placebo:		
Risk Difference (%) [4]		1.98
95% C.I.		(-0.74, 4.70)
p-value		0.498

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
PPD

Population: Intent-to-Treat

Table 212.3
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
Progression Status, n (%)		
No Progression [1]	86 (99%)	75 (99%)
Any Progression	1 (1%)	1 (1%)
Category 2: Low flow nasal cannulae/face mask	0	1 (1%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	1 (1%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	0	0
Death	0	0
Missing [2]	0	0

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
PPD

Population: Intent-to-Treat

Table 212.3
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Sotrovimab (500mg IV) vs. Placebo:		
Odds Ratio [3]		1.11
95% C.I.		(0.07, 18.18)
p-value		0.940
Risk Difference (%) [4]		0.17
95% C.I.		(-3.24, 3.57)
p-value		>0.999

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
PPD

Population: Intent-to-Treat

Table 212.3
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
Progression Status, n (%)		
No Progression [1]	54 (93%)	62 (97%)
Any Progression	4 (7%)	1 (2%)
Category 2: Low flow nasal cannulae/face mask	1 (2%)	1 (2%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	2 (3%)	0
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	1 (2%)	0
Death	0	0
Missing [2]	0	1 (2%)

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
PPD

Population: Intent-to-Treat

Table 212.3
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Sotrovimab (500mg IV) vs. Placebo:		
Odds Ratio [3]		0.45
95% C.I.		(0.08, 2.58)
p-value		0.370
Risk Difference (%) [4]		-3.77
95% C.I.		(-11.56, 4.02)
p-value		0.423

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
PPD

Population: Intent-to-Treat

Table 212.3
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)		Sotrovimab (500mg IV) (N=528)	
Number of subjects in subgroup	62		77	
Progression Status, n (%)				
No Progression [1]	58	(94%)	75	(97%)
Any Progression	3	(5%)	1	(1%)
Category 2: Low flow nasal cannulae/face mask	1	(2%)	1	(1%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	2	(3%)	0	
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	0		0	
Death	0		0	
Missing [2]	1	(2%)	1	(1%)

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
PPD

Population: Intent-to-Treat

Table 212.3
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Sotrovimab (500mg IV) vs. Placebo:		
Odds Ratio [3]		0.38
95% C.I.		(0.07, 2.16)
p-value		0.275
Risk Difference (%) [4]		-3.85
95% C.I.		(-10.93, 3.22)
p-value		0.407

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher's Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
PPD

Population: Intent-to-Treat

Table 212.3
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)		Sotrovimab (500mg IV) (N=528)	
Number of subjects in subgroup	187		166	
Progression Status, n (%)				
No Progression [1]	164	(88%)	164	(99%)
Any Progression	20	(11%)	2	(1%)
Category 2: Low flow nasal cannulae/face mask	11	(6%)	2	(1%)
Category 3: Non-re-breather mask or high flow nasal cannulae/non-invasive ventilation (including continuous positive airway pressure support)	4	(2%)	0	
Category 4: Mechanical ventilation/extra-corporeal membrane oxygenation	3	(2%)	0	
Death	2	(1%)	0	
Missing [2]	3	(2%)	0	

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
PPD

Population: Intent-to-Treat

Table 212.3
Summary and Analysis of Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Sotrovimab (500mg IV) vs. Placebo:		
Odds Ratio [3]		0.09
95% C.I.		(0.02, 0.38)
p-value		0.002
Risk Difference (%) [4]		-11.09
95% C.I.		(-16.09, -6.10)
p-value		<0.001

[1] All subjects status at admission is category 1: room air.
[2] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data were considered to have met the endpoint.
Note: Analysis was performed adjusting for treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and week 24 baseline viral load by treatment interaction, using [3] logistic regression. Poisson model results not presented as neither the full model nor simple model converged.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Subjects are counted in the worst-case progression that they have reported up to the time point.
PPD

Population: Intent-to-Treat

Table 212.4
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	0	0
Hospitalized due to non-respiratory complications	0	0
Death	0	0
Alive and not hospitalized due to non-respiratory complications	97 (100%)	101 (100%)
Missing [1]	0	0

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 212.4
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)		Sotrovimab (500mg IV) (N=528)	
Number of subjects in subgroup	87		76	
Non-Respiratory Complications Status, n (%)				
Hospitalized due to non-respiratory complications and/or Death	2	(2%)	2	(3%)
Hospitalized due to non-respiratory complications	2	(2%)	2	(3%)
Death	0		0	
Alive and not hospitalized due to non-respiratory complications	85	(98%)	74	(97%)
Missing [1]	0		0	

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.

PPD

Population: Intent-to-Treat

Table 212.4
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)		Sotrovimab (500mg IV) (N=528)	
Number of subjects in subgroup	58		64	
Non-Respiratory Complications Status, n (%)				
Hospitalized due to non-respiratory complications and/or Death	1	(2%)	0	
Hospitalized due to non-respiratory complications	1	(2%)	0	
Death	0		0	
Alive and not hospitalized due to non-respiratory complications	56	(97%)	62	(97%)
Missing [1]	1	(2%)	2	(3%)

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 212.4
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)		Sotrovimab (500mg IV) (N=528)	
Number of subjects in subgroup	62		77	
Non-Respiratory Complications Status, n (%)				
Hospitalized due to non-respiratory complications and/or Death	0		1	(1%)
Hospitalized due to non-respiratory complications	0		1	(1%)
Death	0		0	
Alive and not hospitalized due to non-respiratory complications	61	(98%)	75	(97%)
Missing [1]	1	(2%)	1	(1%)

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.

PPD

Population: Intent-to-Treat

Table 212.4
Summary and Analysis of Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
Non-Respiratory Complications Status, n (%)		
Hospitalized due to non-respiratory complications and/or Death	3 (2%)	1 (<1%)
Hospitalized due to non-respiratory complications	1 (<1%)	1 (<1%)
Death	2 (1%)	0
Alive and not hospitalized due to non-respiratory complications	179 (96%)	165 (>99%)
Missing [1]	5 (3%)	0

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing data/death were considered to have met the endpoint.

PPD

Population: Intent-to-Treat

Table 212.5
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization > 24 hours or Death) through Day 29

Interaction of Treatment with:	P-value [1]
Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	NA

[1] Interaction p-values obtained from Poisson models with covariates of treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), subgroup and subgroup by treatment interaction.
Note: NA represents models where neither the full nor simple Poisson model converged.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 212.6
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects Who Have Progression of COVID-19 (Hospitalization or ER visit or Death) through Day 29

Interaction of Treatment with:	P-value [1]
Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	NA

[1] Interaction p-values obtained from Poisson models with covariates of treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), subgroup and subgroup by treatment interaction.
Note: NA represents models where neither the full nor simple Poisson model converged.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 212.7
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects Who Progress to Develop Severe and/or Critical Respiratory COVID-19 through Day 29

Interaction of Treatment with:	P-value [1]
Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	NA

[1] Interaction p-values obtained from Poisson models with covariates of treatment, duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), subgroup and subgroup by treatment interaction.
Note: NA represents models where neither the full nor simple Poisson model converged.
PPD

Population: Intent-to-Treat

Table 212.8
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects Hospitalized Due to Non-Respiratory Complications of COVID-19 through Day 29

Interaction of Treatment with:	P-value [1]
Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	NA

[1] Interaction p-values obtained from Poisson models with covariates of treatment, subgroup and subgroup by treatment interaction.
Note: NA represents models where the Poisson model did not converge.
PPD

Protocol: 214367
Population: Intent-to-Treat

Table 212.9
Summary and Analysis of Time to All-Cause Mortality up to Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

		Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup	97	101
All-cause Mortality to Day 60	Deceased	0	0
	Censored	97 (100%)	101 (100%)
	Alive at day 60	97 (100%)	101 (100%)
	Censored at study withdrawal prior to day 60	0	0
All-cause Mortality to Day 90	Deceased	0	0
	Censored	97 (100%)	101 (100%)
	Alive at day 90	97 (100%)	101 (100%)
	Censored at study withdrawal prior to day 90	0	0

Note: Subjects alive at the end of follow-up were censored at day 60/90, subjects who withdrew prior to occurrence of the event and day 60/90 were censored at the time of study withdrawal.

PPD

Population: Intent-to-Treat

Table 212.9
Summary and Analysis of Time to All-Cause Mortality up to Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

		Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup	87	76
All-cause Mortality to Day 60	Deceased	0	0
	Censored	87 (100%)	76 (100%)
	Alive at day 60	85 (98%)	76 (100%)
	Censored at study withdrawal prior to day 60	2 (2%)	0
All-cause Mortality to Day 90	Deceased	0	0
	Censored	87 (100%)	76 (100%)
	Alive at day 90	85 (98%)	76 (100%)
	Censored at study withdrawal prior to day 90	2 (2%)	0

Note: Subjects alive at the end of follow-up were censored at day 60/90, subjects who withdrew prior to occurrence of the event and day 60/90 were censored at the time of study withdrawal.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 212.9
Summary and Analysis of Time to All-Cause Mortality up to Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

		Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup	58	64
All-cause Mortality to Day 60	Deceased	1 (2%)	0
	Censored	57 (98%)	64 (100%)
	Alive at day 60	56 (97%)	62 (97%)
	Censored at study withdrawal prior to day 60	1 (2%)	2 (3%)
All-cause Mortality to Day 90	Deceased	1 (2%)	0
	Censored	57 (98%)	64 (100%)
	Alive at day 90	56 (97%)	62 (97%)
	Censored at study withdrawal prior to day 90	1 (2%)	2 (3%)

Note: Subjects alive at the end of follow-up were censored at day 60/90, subjects who withdrew prior to occurrence of the event and day 60/90 were censored at the time of study withdrawal.

PPD

Population: Intent-to-Treat

Table 212.9
Summary and Analysis of Time to All-Cause Mortality up to Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

		Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup	62	77
All-cause Mortality to Day 60	Deceased	0	0
	Censored	62 (100%)	77 (100%)
	Alive at day 60	61 (98%)	75 (97%)
	Censored at study withdrawal prior to day 60	1 (2%)	2 (3%)
All-cause Mortality to Day 90	Deceased	0	0
	Censored	62 (100%)	77 (100%)
	Alive at day 90	61 (98%)	75 (97%)
	Censored at study withdrawal prior to day 90	1 (2%)	2 (3%)

Note: Subjects alive at the end of follow-up were censored at day 60/90, subjects who withdrew prior to occurrence of the event and day 60/90 were censored at the time of study withdrawal.

PPD

Population: Intent-to-Treat

Table 212.9
Summary and Analysis of Time to All-Cause Mortality up to Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

		Placebo (N=529)		Sotrovimab (500mg IV) (N=528)	
	Number of subjects in subgroup	187		166	
All-cause Mortality to Day 60	Deceased	3	(2%)	0	
	Censored	184	(98%)	166	(100%)
	Alive at day 60	179	(96%)	166	(100%)
	Censored at study withdrawal prior to day 60	5	(3%)	0	
All-cause Mortality to Day 90	Deceased	3	(2%)	0	
	Censored	184	(98%)	166	(100%)
	Alive at day 90	178	(95%)	166	(100%)
	Censored at study withdrawal prior to day 90	6	(3%)	0	

Note: Subjects alive at the end of follow-up were censored at day 60/90, subjects who withdrew prior to occurrence of the event and day 60/90 were censored at the time of study withdrawal.

PPD

Table 212.10
P-values for Interactions of Treatment with Subgroups for Time to All-Cause Mortality up to Day 90

No data to report

PPD

Population: Intent-to-Treat

Table 212.11
Summary of Duration on Ventilator through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
Alive and never on ventilation [1]	97 (100%)	101 (100%)
On ventilation [2]	0	0
1 period	0	0
2 periods	0	0
>2 periods	0	0
Incomplete follow-up due to study withdrawal	0	0
On ventilation prior to study withdrawal	0	0
Withdrawn and never on ventilation	0	0
Incomplete follow-up due to death [3]	0	0
On ventilation prior to death	0	0
Deceased and never on ventilation	0	0
Ventilator use [3]		
0 days	97 (100%)	101 (100%)
1 - <=8 days	0	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 212.11
Summary of Duration on Ventilator through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.0	0.0
SD	0.00	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	0	0
Duration (days) - Subjects with event/death [3]		
n	0	0
Mean		
SD		
Median		
IQR		
Min.		
Max.		

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.
PPD

Table 212.11
Summary of Duration on Ventilator through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
Alive and never on ventilation [1]	85 (98%)	76 (100%)
On ventilation [2]	0	0
1 period	0	0
2 periods	0	0
>2 periods	0	0
Incomplete follow-up due to study withdrawal	2 (2%)	0
On ventilation prior to study withdrawal	0	0
Withdrawn and never on ventilation	2 (2%)	0
Incomplete follow-up due to death [3]	0	0
On ventilation prior to death	0	0
Deceased and never on ventilation	0	0
Ventilator use [3]		
0 days	87 (100%)	76 (100%)
1 - <=8 days	0	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 212.11
Summary of Duration on Ventilator through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.0	0.0
SD	0.00	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	0	0
Duration (days) - Subjects with event/death [3]		
n	0	0
Mean		
SD		
Median		
IQR		
Min.		
Max.		

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.11
Summary of Duration on Ventilator through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)		Sotrovimab (500mg IV) (N=528)	
Number of subjects in subgroup	58		64	
Alive and never on ventilation [1]	56	(97%)	62	(97%)
On ventilation [2]	1	(2%)	0	
1 period	1	(2%)	0	
2 periods	0		0	
>2 periods	0		0	
Incomplete follow-up due to study withdrawal	1	(2%)	2	(3%)
On ventilation prior to study withdrawal	0		0	
Withdrawn and never on ventilation	1	(2%)	2	(3%)
Incomplete follow-up due to death [3]	1	(2%)	0	
On ventilation prior to death	1	(2%)	0	
Deceased and never on ventilation	0		0	
Ventilator use [3]				
0 days	57	(98%)	64	(100%)
1 - <=8 days	0		0	
9 - <=15 days	0		0	
16 - <=22 days	0		0	
23 - <=29 days	0		0	
30 - <=59 days	0		0	
60 - <=90 days	1	(2%)	0	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 212.11
Summary of Duration on Ventilator through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	1.3	0.0
SD	10.11	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	77	0
Duration (days) - Subjects with event/death [3]		
n	1	0
Mean	77.0	
SD		
Median	77.0	
IQR	77.0 - 77.0	
Min.	77	
Max.	77	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Table 212.11
Summary of Duration on Ventilator through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	62	77
Alive and never on ventilation [1]	61 (98%)	75 (97%)
On ventilation [2]	0	0
1 period	0	0
2 periods	0	0
>2 periods	0	0
Incomplete follow-up due to study withdrawal	1 (2%)	2 (3%)
On ventilation prior to study withdrawal	0	0
Withdrawn and never on ventilation	1 (2%)	2 (3%)
Incomplete follow-up due to death [3]	0	0
On ventilation prior to death	0	0
Deceased and never on ventilation	0	0
Ventilator use [3]		
0 days	62 (100%)	77 (100%)
1 - <=8 days	0	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 212.11
Summary of Duration on Ventilator through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.0	0.0
SD	0.00	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	0	0
Duration (days) - Subjects with event/death [3]		
n	0	0
Mean		
SD		
Median		
IQR		
Min.		
Max.		

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.11
Summary of Duration on Ventilator through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
Alive and never on ventilation [1]	176 (94%)	166 (100%)
On ventilation [2]	3 (2%)	0
1 period	3 (2%)	0
2 periods	0	0
>2 periods	0	0
Incomplete follow-up due to study withdrawal	6 (3%)	0
On ventilation prior to study withdrawal	0	0
Withdrawn and never on ventilation	6 (3%)	0
Incomplete follow-up due to death [3]	3 (2%)	0
On ventilation prior to death	1 (<1%)	0
Deceased and never on ventilation	2 (1%)	0
Ventilator use [3]		
0 days	182 (97%)	166 (100%)
1 - <=8 days	0	0
9 - <=15 days	1 (<1%)	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	1 (<1%)	0
60 - <=90 days	3 (2%)	0

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 212.11
Summary of Duration on Ventilator through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	1.6	0.0
SD	10.45	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	0
Duration (days) - Subjects with event/death [3]		
n	5	0
Mean	58.2	
SD	30.88	
Median	71.0	
IQR	48.0 - 77.0	
Min.	9	
Max.	86	

[1] Alive and never on ventilation based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate period of ventilation.
[3] Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.12
Analysis of Duration (days) on Ventilator through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
n	97	101
LS Mean (SE)	0.0 (0.53)	0.0 (0.52)
95% C.I.	(-1.0, 1.0)	(-1.0, 1.0)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.0 (0.74)
95% C.I.		(-1.5, 1.5)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		0.0 (0.14)
95% C.I.		(-0.3, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.12
Analysis of Duration (days) on Ventilator through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
n	87	76
LS Mean (SE)	0.0 (0.56)	0.0 (0.60)
95% C.I.	(-1.1, 1.1)	(-1.2, 1.2)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.0 (0.82)
95% C.I.		(-1.6, 1.6)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		0.0 (0.16)
95% C.I.		(-0.3, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.12
Analysis of Duration (days) on Ventilator through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
n	58	64
LS Mean (SE)	1.3 (0.68)	0.0 (0.65)
95% C.I.	(0.0, 2.7)	(-1.3, 1.3)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.3 (0.94)
95% C.I.		(-3.2, 0.5)
p-value		0.160
Corrected Hedge’s g (SE) [1]		-0.3 (0.18)
95% C.I.		(-0.6, 0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.12
Analysis of Duration (days) on Ventilator through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	62	77
n	62	77
LS Mean (SE)	0.0 (0.66)	0.0 (0.59)
95% C.I.	(-1.3, 1.3)	(-1.2, 1.2)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.0 (0.89)
95% C.I.		(-1.7, 1.7)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		0.0 (0.17)
95% C.I.		(-0.3, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.12
Analysis of Duration (days) on Ventilator through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
n	187	166
LS Mean (SE)	1.6 (0.38)	0.0 (0.40)
95% C.I.	(0.8, 2.3)	(-0.8, 0.8)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.6 (0.55)
95% C.I.		(-2.6, -0.5)
p-value		0.006
Corrected Hedge’s g (SE) [1]		-0.3 (0.11)
95% C.I.		(-0.5, -0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be on ventilation from date of death until day 90.
Note: Ventilation use is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 212.13
Summary of Duration in Intensive Care Unit through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
Alive and never entered ICU [1]	97 (100%)	101 (100%)
Entered ICU [2]	0	0
1 stay	0	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	0	0
Entered ICU prior to study withdrawal	0	0
Withdrawn and never entered ICU	0	0
Incomplete follow-up due to death [3]	0	0
Entered ICU prior to death	0	0
Deceased and never entered ICU	0	0
ICU Stay [3]		
0 days	97 (100%)	101 (100%)
1 - <=8 days	0	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.13
Summary of Duration in Intensive Care Unit through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.0	0.0
SD	0.00	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	0	0
Duration (days) - Subjects with event/death [3]		
n	0	0
Mean		
SD		
Median		
IQR		
Min.		
Max.		

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 212.13
Summary of Duration in Intensive Care Unit through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
Alive and never entered ICU [1]	85 (98%)	76 (100%)
Entered ICU [2]	1 (1%)	0
1 stay	1 (1%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	2 (2%)	0
Entered ICU prior to study withdrawal	1 (1%)	0
Withdrawn and never entered ICU	1 (1%)	0
Incomplete follow-up due to death [3]	0	0
Entered ICU prior to death	0	0
Deceased and never entered ICU	0	0
ICU Stay [3]		
0 days	86 (99%)	76 (100%)
1 - <=8 days	1 (1%)	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.
PPD

Table 212.13
Summary of Duration in Intensive Care Unit through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.1	0.0
SD	0.64	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	6	0
Duration (days) - Subjects with event/death [3]		
n	1	0
Mean	6.0	
SD		
Median	6.0	
IQR	6.0 - 6.0	
Min.	6	
Max.	6	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 212.13
Summary of Duration in Intensive Care Unit through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)		Sotrovimab (500mg IV) (N=528)	
Number of subjects in subgroup	58		64	
Alive and never entered ICU [1]	55	(95%)	62	(97%)
Entered ICU [2]	2	(3%)	0	
1 stay	2	(3%)	0	
2 stays	0		0	
>2 stays	0		0	
Incomplete follow-up due to study withdrawal	1	(2%)	2	(3%)
Entered ICU prior to study withdrawal	0		0	
Withdrawn and never entered ICU	1	(2%)	2	(3%)
Incomplete follow-up due to death [3]	1	(2%)	0	
Entered ICU prior to death	1	(2%)	0	
Deceased and never entered ICU	0		0	
ICU Stay [3]				
0 days	56	(97%)	64	(100%)
1 - <=8 days	0		0	
9 - <=15 days	0		0	
16 - <=22 days	0		0	
23 - <=29 days	1	(2%)	0	
30 - <=59 days	0		0	
60 - <=90 days	1	(2%)	0	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Table 212.13
Summary of Duration in Intensive Care Unit through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	1.8	0.0
SD	11.04	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	81	0
Duration (days) - Subjects with event/death [3]		
n	2	0
Mean	52.5	
SD	40.31	
Median	52.5	
IQR	24.0 - 81.0	
Min.	24	
Max.	81	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 212.13
Summary of Duration in Intensive Care Unit through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	62	77
Alive and never entered ICU [1]	61 (98%)	75 (97%)
Entered ICU [2]	0	0
1 stay	0	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	1 (2%)	2 (3%)
Entered ICU prior to study withdrawal	0	0
Withdrawn and never entered ICU	1 (2%)	2 (3%)
Incomplete follow-up due to death [3]	0	0
Entered ICU prior to death	0	0
Deceased and never entered ICU	0	0
ICU Stay [3]		
0 days	62 (100%)	77 (100%)
1 - <=8 days	0	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 212.13
Summary of Duration in Intensive Care Unit through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	0.0	0.0
SD	0.00	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	0	0
Duration (days) - Subjects with event/death [3]		
n	0	0
Mean		
SD		
Median		
IQR		
Min.		
Max.		

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.13
Summary of Duration in Intensive Care Unit through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
Alive and never entered ICU [1]	174 (93%)	166 (100%)
Entered ICU [2]	6 (3%)	0
1 stay	6 (3%)	0
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	6 (3%)	0
Entered ICU prior to study withdrawal	0	0
Withdrawn and never entered ICU	6 (3%)	0
Incomplete follow-up due to death [3]	3 (2%)	0
Entered ICU prior to death	2 (1%)	0
Deceased and never entered ICU	1 (<1%)	0
ICU Stay [3]		
0 days	180 (96%)	166 (100%)
1 - <=8 days	1 (<1%)	0
9 - <=15 days	2 (1%)	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	1 (<1%)	0
60 - <=90 days	3 (2%)	0

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.13
Summary of Duration in Intensive Care Unit through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - All subjects [3]		
Mean	1.6	0.0
SD	10.33	0.00
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	0
Duration (days) - Subjects with event/death [3]		
n	7	0
Mean	43.3	
SD	34.69	
Median	37.0	
IQR	9.0 - 77.0	
Min.	8	
Max.	86	

[1] Alive and never entered the intensive care unit based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate ICU stay.
[3] Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.14
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
n	97	101
LS Mean (SE)	0.0 (0.54)	0.0 (0.52)
95% C.I.	(-1.1, 1.1)	(-1.0, 1.0)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.0 (0.75)
95% C.I.		(-1.5, 1.5)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		0.0 (0.14)
95% C.I.		(-0.3, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.14
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
n	87	76
LS Mean (SE)	0.1 (0.57)	0.0 (0.60)
95% C.I.	(-1.0, 1.2)	(-1.2, 1.2)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.1 (0.83)
95% C.I.		(-1.7, 1.6)
p-value		0.934
Corrected Hedge’s g (SE) [1]		0.0 (0.16)
95% C.I.		(-0.3, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.14
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
n	58	64
LS Mean (SE)	1.8 (0.69)	0.0 (0.66)
95% C.I.	(0.5, 3.2)	(-1.3, 1.3)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.8 (0.96)
95% C.I.		(-3.7, 0.1)
p-value		0.059
Corrected Hedge’s g (SE) [1]		-0.3 (0.18)
95% C.I.		(-0.7, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.14
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	62	77
n	62	77
LS Mean (SE)	0.0 (0.67)	0.0 (0.60)
95% C.I.	(-1.3, 1.3)	(-1.2, 1.2)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.0 (0.90)
95% C.I.		(-1.8, 1.8)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		0.0 (0.17)
95% C.I.		(-0.3, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.14
Analysis of Duration (days) in Intensive Care Unit through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
n	187	166
LS Mean (SE)	1.6 (0.39)	0.0 (0.41)
95% C.I.	(0.9, 2.4)	(-0.8, 0.8)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.6 (0.56)
95% C.I.		(-2.7, -0.5)
p-value		0.005
Corrected Hedge’s g (SE) [1]		-0.3 (0.11)
95% C.I.		(-0.5, -0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in the intensive care unit from date of death until day 90.
Note: Time spent in the intensive care unit is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.15
Summary of Duration in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
Alive and never entered hospital [1]	97 (100%)	99 (98%)
Entered hospital [2]	0	2 (2%)
1 stay	0	2 (2%)
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	0	0
Entered hospital prior to study withdrawal	0	0
Withdrawn and never entered hospital	0	0
Incomplete follow-up due to death [3]	0	0
Entered hospital prior to death	0	0
Deceased and never entered hospital	0	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.
PPD

Table 212.15
Summary of Duration in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	97 (100%)	99 (98%)
>0 - <=24 hours	0	1 (<1%)
>1 - <=8 days	0	0
9 - <=15 days	0	1 (<1%)
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0
Duration (days) - All subjects [3]		
Mean	0.0	0.1
SD	0.00	1.40
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	0	14

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Table 212.15
Summary of Duration in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	0	2
Mean		7.5
SD		9.19
Median		7.5
IQR		1.0 - 14.0
Min.		1
Max.		14

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 212.15
Summary of Duration in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
Alive and never entered hospital [1]	83 (95%)	74 (97%)
Entered hospital [2]	3 (3%)	2 (3%)
1 stay	3 (3%)	1 (1%)
2 stays	0	1 (1%)
>2 stays	0	0
Incomplete follow-up due to study withdrawal	2 (2%)	0
Entered hospital prior to study withdrawal	1 (1%)	0
Withdrawn and never entered hospital	1 (1%)	0
Incomplete follow-up due to death [3]	0	0
Entered hospital prior to death	0	0
Deceased and never entered hospital	0	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.15
Summary of Duration in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	84 (97%)	74 (97%)
>0 - <=24 hours	0	0
>1 - <=8 days	3 (3%)	1 (1%)
9 - <=15 days	0	1 (1%)
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0
Duration (days) - All subjects [3]		
Mean	0.1	0.3
SD	0.83	1.55
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	6	11

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.15
Summary of Duration in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	3	2
Mean	4.3	9.5
SD	1.53	2.12
Median	4.0	9.5
IQR	3.0 - 6.0	8.0 - 11.0
Min.	3	8
Max.	6	11

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 212.15
Summary of Duration in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
Alive and never entered hospital [1]	53 (91%)	62 (97%)
Entered hospital [2]	5 (9%)	1 (2%)
1 stay	4 (7%)	1 (2%)
2 stays	1 (2%)	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	1 (2%)	2 (3%)
Entered hospital prior to study withdrawal	1 (2%)	1 (2%)
Withdrawn and never entered hospital	0	1 (2%)
Incomplete follow-up due to death [3]	1 (2%)	0
Entered hospital prior to death	1 (2%)	0
Deceased and never entered hospital	0	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 212.15
Summary of Duration in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	53 (91%)	63 (98%)
>0 - <=24 hours	0	0
>1 - <=8 days	2 (3%)	1 (2%)
9 - <=15 days	1 (2%)	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	1 (2%)	0
60 - <=90 days	1 (2%)	0
Duration (days) - All subjects [3]		
Mean	2.3	0.1
SD	11.42	0.63
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	81	5

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.15
Summary of Duration in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	5	1
Mean	26.4	5.0
SD	32.61	
Median	11.0	5.0
IQR	4.0 - 32.0	5.0 - 5.0
Min.	4	5
Max.	81	5

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.15
Summary of Duration in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	62	77
Alive and never entered hospital [1]	58 (94%)	74 (96%)
Entered hospital [2]	3 (5%)	1 (1%)
1 stay	3 (5%)	1 (1%)
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	1 (2%)	2 (3%)
Entered hospital prior to study withdrawal	0	0
Withdrawn and never entered hospital	1 (2%)	2 (3%)
Incomplete follow-up due to death [3]	0	0
Entered hospital prior to death	0	0
Deceased and never entered hospital	0	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.15
Summary of Duration in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	59 (95%)	76 (99%)
>0 - <=24 hours	0	1 (1%)
>1 - <=8 days	3 (5%)	0
9 - <=15 days	0	0
16 - <=22 days	0	0
23 - <=29 days	0	0
30 - <=59 days	0	0
60 - <=90 days	0	0
Duration (days) - All subjects [3]		
Mean	0.3	0.0
SD	1.53	0.11
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	8	1

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.15
Summary of Duration in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	3	1
Mean	7.0	1.0
SD	1.00	
Median	7.0	1.0
IQR	6.0 - 8.0	1.0 - 1.0
Min.	6	1
Max.	8	1

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.15
Summary of Duration in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
Alive and never entered hospital [1]	163 (87%)	162 (98%)
Entered hospital [2]	19 (10%)	4 (2%)
1 stay	19 (10%)	4 (2%)
2 stays	0	0
>2 stays	0	0
Incomplete follow-up due to study withdrawal	6 (3%)	0
Entered hospital prior to study withdrawal	2 (1%)	0
Withdrawn and never entered hospital	4 (2%)	0
Incomplete follow-up due to death [3]	3 (2%)	0
Entered hospital prior to death	2 (1%)	0
Deceased and never entered hospital	1 (<1%)	0

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Population: Intent-to-Treat

Table 212.15
Summary of Duration in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Hospital Stay [3]		
0 days	167 (89%)	162 (98%)
>0 - <=24 hours	0	0
>1 - <=8 days	12 (6%)	2 (1%)
9 - <=15 days	2 (1%)	0
16 - <=22 days	2 (1%)	1 (<1%)
23 - <=29 days	0	0
30 - <=59 days	1 (<1%)	1 (<1%)
60 - <=90 days	3 (2%)	0
Duration (days) - All subjects [3]		
Mean	2.2	0.4
SD	11.43	4.16
Median	0.0	0.0
IQR	0.0 - 0.0	0.0 - 0.0
Min.	0	0
Max.	86	51

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.15
Summary of Duration in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Duration (days) - Subjects with event/death [3]		
n	20	4
Mean	21.0	18.5
SD	29.38	22.46
Median	6.5	10.0
IQR	4.5 - 18.0	3.5 - 33.5
Min.	2	3
Max.	86	51

[1] Alive and never entered hospital based on complete follow-up data up to day 90.
[2] A break of >24 hours is considered to be a separate hospital stay.
[3] Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 212.16
Analysis of Duration (days) in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
n	97	101
LS Mean (SE)	0.0 (0.61)	0.1 (0.60)
95% C.I.	(-1.2, 1.2)	(-1.0, 1.3)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.1 (0.86)
95% C.I.		(-1.5, 1.8)
p-value		0.863
Corrected Hedge’s g (SE) [1]		0.0 (0.14)
95% C.I.		(-0.3, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.16
Analysis of Duration (days) in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
n	87	76
LS Mean (SE)	0.1 (0.65)	0.3 (0.69)
95% C.I.	(-1.1, 1.4)	(-1.1, 1.6)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.1 (0.95)
95% C.I.		(-1.8, 2.0)
p-value		0.916
Corrected Hedge’s g (SE) [1]		0.0 (0.16)
95% C.I.		(-0.3, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.16
Analysis of Duration (days) in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
n	58	64
LS Mean (SE)	2.3 (0.79)	0.1 (0.75)
95% C.I.	(0.7, 3.8)	(-1.4, 1.6)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-2.2 (1.09)
95% C.I.		(-4.3, 0.0)
p-value		0.045
Corrected Hedge’s g (SE) [1]		-0.4 (0.18)
95% C.I.		(-0.7, 0.0)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.16
Analysis of Duration (days) in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	62	77
n	62	77
LS Mean (SE)	0.3 (0.77)	0.0 (0.69)
95% C.I.	(-1.2, 1.8)	(-1.3, 1.4)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.3 (1.03)
95% C.I.		(-2.3, 1.7)
p-value		0.752
Corrected Hedge’s g (SE) [1]		-0.1 (0.17)
95% C.I.		(-0.4, 0.3)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.16
Analysis of Duration (days) in Hospital through Day 90 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
n	187	166
LS Mean (SE)	2.2 (0.44)	0.4 (0.47)
95% C.I.	(1.4, 3.1)	(-0.5, 1.4)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.8 (0.64)
95% C.I.		(-3.1, -0.5)
p-value		0.006
Corrected Hedge’s g (SE) [1]		-0.3 (0.11)
95% C.I.		(-0.5, -0.1)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Note: Subjects who died prior to day 90 were considered to be in hospital from date of death until day 90.
Note: Time spent in hospital is assessed from the date of randomization for 90 days.
PPD

Population: Intent-to-Treat

Table 212.17
P-values for Interactions of Treatment with Subgroups for Duration on Ventilator through Day 90

Interaction of Treatment with:	P-value [1]
Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.282

[1] Interaction p-values obtained from ANCOVA model, adjusting for treatment, subgroup and subgroup by treatment interaction.

PPD

Table 212.18
P-values for Interactions of Treatment with Subgroups for Duration in Intensive Care Unit through Day 90

Interaction of Treatment with:	P-value [1]
Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.204

[1] Interaction p-values obtained from ANCOVA model, adjusting for treatment, subgroup and subgroup by treatment interaction.

PPD

Population: Intent-to-Treat

Table 212.19
P-values for Interactions of Treatment with Subgroups for Duration in Hospital through Day 90

Interaction of Treatment with:	P-value [1]
Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.181

[1] Interaction p-values obtained from ANCOVA model, adjusting for treatment, subgroup and subgroup by treatment interaction.

PPD

Protocol: 214367
Population: Week 24 Virology

Table 212.20
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Baseline	Viral Load (log10 copies/mL)	n	394	383
		Mean	6.639	6.538
		SD	1.6733	1.6452
		Median	6.830	6.596
		Min.	3.367	3.373
		Max.	10.040	10.009
Day 5	Viral Load (log10 copies/mL)	n	338	337
		Mean	5.213	4.723
		SD	1.7550	1.4600
		Median	5.068	4.473
		Min.	2.873	2.873
		Max.	9.614	8.830
	Change from Baseline (log10 copies/mL)	n	338	337
		Mean	-1.454	-1.889
		SD	1.5065	1.3352
		Median	-1.515	-1.880
		Min.	-5.210	-5.251
		Max.	3.455	3.306

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 212.20
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Day 8	Viral Load (log10 copies/mL)	n	338	333
		Mean	4.278	3.997
		SD	1.3678	1.2014
		Median	3.914	3.545
		Min.	2.873	2.873
		Max.	8.416	8.231
	Change from Baseline (log10 copies/mL)	n	338	333
		Mean	-2.404	-2.618
		SD	1.5118	1.4626
		Median	-2.418	-2.723
		Min.	-5.875	-5.981
		Max.	4.615	2.328
Day 11	Viral Load (log10 copies/mL)	n	330	334
		Mean	3.858	3.723
		SD	1.1556	1.0692
		Median	3.270	3.270
		Min.	2.873	2.873
		Max.	8.470	8.398
	Change from Baseline (log10 copies/mL)	n	330	334
		Mean	-2.779	-2.819
		SD	1.6019	1.6358
		Median	-2.872	-2.919
		Min.	-6.265	-6.487
		Max.	4.647	2.561

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 212.20
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Day 15	Viral Load (log10 copies/mL)	n	311	314
		Mean	3.435	3.376
		SD	0.8340	0.7219
		Median	3.270	3.270
		Min.	2.873	2.873
		Max.	7.450	8.007
	Change from Baseline (log10 copies/mL)	n	311	314
		Mean	-3.149	-3.189
		SD	1.5923	1.5159
		Median	-3.098	-3.333
		Min.	-7.068	-6.480
		Max.	3.108	0.778
Day 22	Viral Load (log10 copies/mL)	n	312	319
		Mean	3.187	3.068
		SD	0.5661	0.3774
		Median	2.873	2.873
		Min.	2.873	2.873
		Max.	6.625	6.471
	Change from Baseline (log10 copies/mL)	n	312	319
		Mean	-3.392	-3.463
		SD	1.5955	1.5760
		Median	-3.434	-3.518
		Min.	-7.068	-6.877
		Max.	1.291	0.393

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 212.20
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Day 29	Viral Load (log10 copies/mL)	n	331	328
		Mean	3.039	3.016
		SD	0.3892	0.3802
		Median	2.873	2.873
		Min.	2.873	2.873
		Max.	5.825	6.178
	Change from Baseline (log10 copies/mL)	n	331	328
		Mean	-3.518	-3.451
		SD	1.6247	1.6293
		Median	-3.726	-3.504
		Min.	-7.068	-7.112
		Max.	0.323	-0.355

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Protocol: 214367
Population: Week 24 Virology

Table 212.21
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit: Day 5

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	382	378
n [2]	338	337
LS Mean (SE)	5.159 (0.0678)	4.696 (0.0678)
95% C.I.	(5.026, 5.293)	(4.563, 4.829)
LS Mean Change from Baseline (SE)	-1.413 (0.0678)	-1.877 (0.0678)
95% C.I.	(-1.547, -1.280)	(-2.010, -1.744)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.463 (0.0959)
95% C.I.		(-0.652, -0.275)
p-value		<0.001
Corrected Hedge’s g (SE) [3]		-0.371 (0.0776)
95% C.I.		(-0.524, -0.219)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline, visit, week 24 baseline by visit and treatment by visit interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.21
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit: Day 8

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	382	378
n [2]	338	333
LS Mean (SE)	4.237 (0.0581)	3.967 (0.0583)
95% C.I.	(4.123, 4.352)	(3.853, 4.082)
LS Mean Change from Baseline (SE)	-2.335 (0.0581)	-2.605 (0.0583)
95% C.I.	(-2.449, -2.221)	(-2.720, -2.491)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.270 (0.0823)
95% C.I.		(-0.432, -0.109)
p-value		0.001
Corrected Hedge’s g (SE) [3]		-0.253 (0.0775)
95% C.I.		(-0.405, -0.101)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline, visit, week 24 baseline by visit and treatment by visit interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.21
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit: Day 11

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	382	378
n [2]	330	334
LS Mean (SE)	3.848 (0.0546)	3.714 (0.0544)
95% C.I.	(3.741, 3.955)	(3.608, 3.821)
LS Mean Change from Baseline (SE)	-2.725 (0.0546)	-2.858 (0.0544)
95% C.I.	(-2.832, -2.618)	(-2.965, -2.752)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.133 (0.0771)
95% C.I.		(-0.285, 0.018)
p-value		0.084
Corrected Hedge’s g (SE) [3]		-0.134 (0.0777)
95% C.I.		(-0.286, 0.018)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline, visit, week 24 baseline by visit and treatment by visit interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.21
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit: Day 15

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	382	378
n [2]	311	314
LS Mean (SE)	3.417 (0.0390)	3.359 (0.0388)
95% C.I.	(3.340, 3.493)	(3.283, 3.436)
LS Mean Change from Baseline (SE)	-3.156 (0.0390)	-3.213 (0.0388)
95% C.I.	(-3.233, -3.080)	(-3.290, -3.137)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.057 (0.0550)
95% C.I.		(-0.165, 0.051)
p-value		0.298
Corrected Hedge’s g (SE) [3]		-0.083 (0.0800)
95% C.I.		(-0.240, 0.074)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline, visit, week 24 baseline by visit and treatment by visit interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.21
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

Visit: Day 22

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	382	378
n [2]	312	319
LS Mean (SE)	3.182 (0.0244)	3.075 (0.0242)
95% C.I.	(3.134, 3.230)	(3.028, 3.123)
LS Mean Change from Baseline (SE)	-3.391 (0.0244)	-3.498 (0.0242)
95% C.I.	(-3.438, -3.343)	(-3.545, -3.450)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.107 (0.0344)
95% C.I.		(-0.174, -0.039)
p-value		0.002
Corrected Hedge’s g (SE) [3]		-0.248 (0.0799)
95% C.I.		(-0.404, -0.091)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline, visit, week 24 baseline by visit and treatment by visit interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.21
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL)

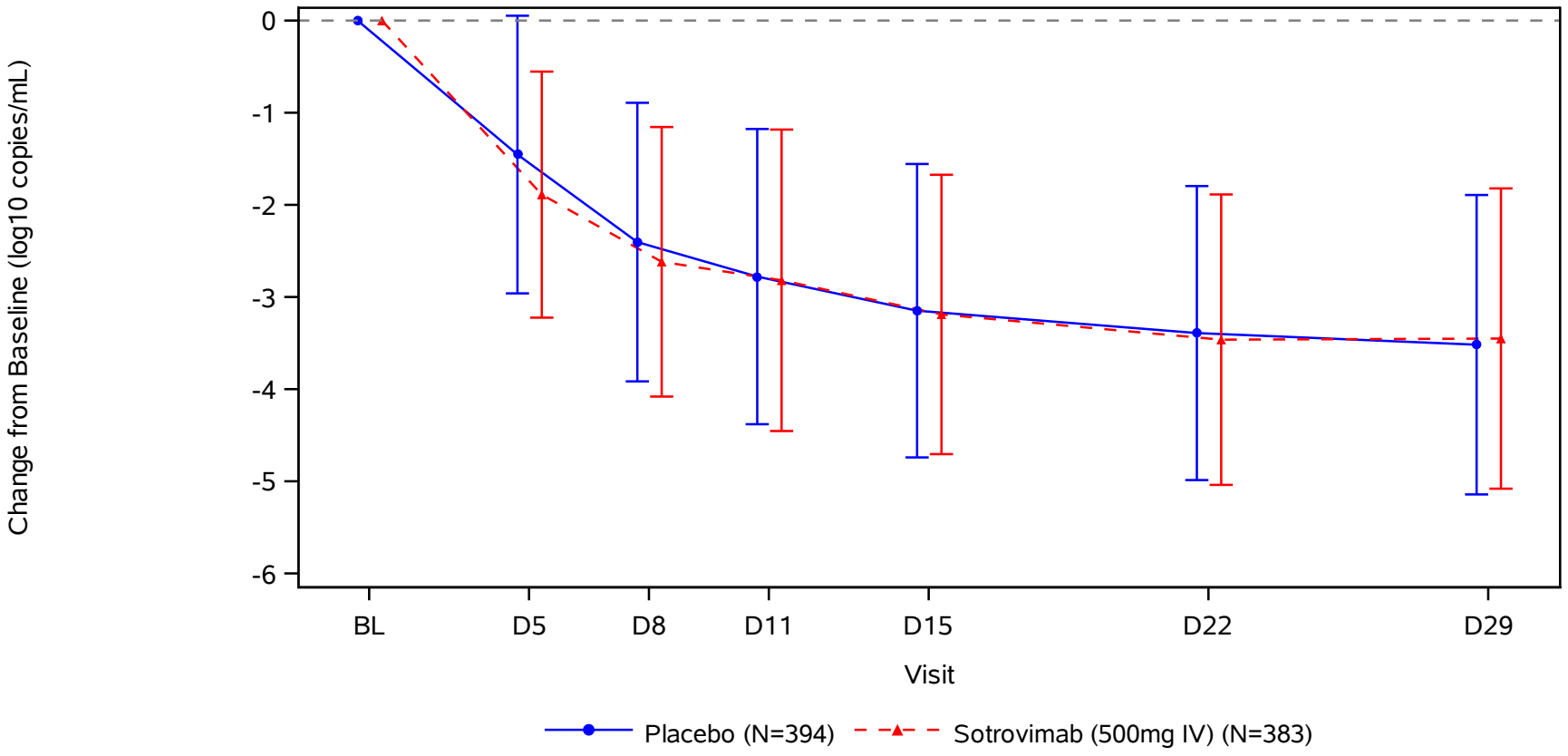
Visit: Day 29

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	382	378
n [2]	331	328
LS Mean (SE)	3.047 (0.0199)	3.025 (0.0199)
95% C.I.	(3.008, 3.086)	(2.986, 3.064)
LS Mean Change from Baseline (SE)	-3.526 (0.0199)	-3.548 (0.0199)
95% C.I.	(-3.565, -3.487)	(-3.587, -3.509)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.022 (0.0282)
95% C.I.		(-0.077, 0.034)
p-value		0.442
Corrected Hedge’s g (SE) [3]		-0.060 (0.0779)
95% C.I.		(-0.213, 0.093)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline, visit, week 24 baseline by visit and treatment by visit interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Protocol: 214367
Population: Week 24 Virology

Figure 212.1
Plot of Mean (+/- SD) Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load



Placebo (n)	394	338	338	330	311	312	331
Sotrovimab (500mg IV) (n)	383	337	333	334	314	319	328

Note: BL=Baseline.

PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 5

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	87	76
n [1]	87	76
n [2]	72	60
LS Mean (SE)	3.769 (0.1510)	3.432 (0.1642)
95% C.I.	(3.472, 4.065)	(3.110, 3.754)
LS Mean Change from Baseline (SE)	-0.516 (0.1471)	-0.676 (0.1601)
95% C.I.	(-0.804, -0.227)	(-0.990, -0.362)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.160 (0.2173)
95% C.I.		(-0.587, 0.266)
Corrected Hedge’s g (SE) [3]		-0.128 (0.1750)
95% C.I.		(-0.471, 0.215)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 8

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	87	76
n [2]	74	60
LS Mean (SE)	3.376 (0.1273)	3.178 (0.1390)
95% C.I.	(3.127, 3.626)	(2.905, 3.451)
LS Mean Change from Baseline (SE)	-0.911 (0.1261)	-0.947 (0.1377)
95% C.I.	(-1.158, -0.663)	(-1.218, -0.677)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.036 (0.1866)
95% C.I.		(-0.403, 0.330)
Corrected Hedge’s g (SE) [3]		-0.034 (0.1737)
95% C.I.		(-0.374, 0.307)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 11

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	87	76
n [2]	74	71
LS Mean (SE)	3.319 (0.1166)	3.203 (0.1212)
95% C.I.	(3.090, 3.548)	(2.965, 3.441)
LS Mean Change from Baseline (SE)	-0.960 (0.1212)	-0.916 (0.1262)
95% C.I.	(-1.198, -0.722)	(-1.164, -0.668)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.044 (0.1749)
95% C.I.		(-0.300, 0.387)
Corrected Hedge’s g (SE) [3]		0.041 (0.1661)
95% C.I.		(-0.285, 0.367)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 15

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	87	76
n [2]	74	62
LS Mean (SE)	3.089 (0.0815)	3.067 (0.0882)
95% C.I.	(2.929, 3.249)	(2.893, 3.240)
LS Mean Change from Baseline (SE)	-1.191 (0.0921)	-1.053 (0.0993)
95% C.I.	(-1.371, -1.010)	(-1.248, -0.858)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.138 (0.1352)
95% C.I.		(-0.127, 0.404)
Corrected Hedge’s g (SE) [3]		0.174 (0.1725)
95% C.I.		(-0.164, 0.512)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 22

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	87	76
n [2]	75	63
LS Mean (SE)	2.984 (0.0505)	2.968 (0.0547)
95% C.I.	(2.885, 3.083)	(2.861, 3.075)
LS Mean Change from Baseline (SE)	-1.287 (0.0725)	-1.150 (0.0776)
95% C.I.	(-1.429, -1.145)	(-1.302, -0.998)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.137 (0.1060)
95% C.I.		(-0.071, 0.345)
Corrected Hedge’s g (SE) [3]		0.219 (0.1714)
95% C.I.		(-0.117, 0.555)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	87	76
n [2]	80	73
LS Mean (SE)	2.931 (0.0411)	2.921 (0.0432)
95% C.I.	(2.850, 3.011)	(2.837, 3.006)
LS Mean Change from Baseline (SE)	-1.342 (0.0692)	-1.198 (0.0729)
95% C.I.	(-1.478, -1.206)	(-1.341, -1.055)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.144 (0.1003)
95% C.I.		(-0.053, 0.341)
Corrected Hedge’s g (SE) [3]		0.231 (0.1624)
95% C.I.		(-0.087, 0.549)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 5

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	58	64
n [1]	57	62
n [2]	51	56
LS Mean (SE)	4.350 (0.1817)	4.013 (0.1731)
95% C.I.	(3.993, 4.707)	(3.673, 4.352)
LS Mean Change from Baseline (SE)	-1.182 (0.1768)	-1.484 (0.1686)
95% C.I.	(-1.530, -0.835)	(-1.815, -1.153)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.302 (0.2443)
95% C.I.		(-0.781, 0.178)
Corrected Hedge’s g (SE) [3]		-0.237 (0.1942)
95% C.I.		(-0.618, 0.143)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 8

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	57	62
n [2]	50	58
LS Mean (SE)	3.772 (0.1557)	3.751 (0.1465)
95% C.I.	(3.466, 4.077)	(3.464, 4.039)
LS Mean Change from Baseline (SE)	-1.766 (0.1543)	-1.745 (0.1451)
95% C.I.	(-2.069, -1.463)	(-2.029, -1.460)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.021 (0.2118)
95% C.I.		(-0.394, 0.437)
Corrected Hedge’s g (SE) [3]		0.019 (0.1930)
95% C.I.		(-0.359, 0.398)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 11

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	57	62
n [2]	52	52
LS Mean (SE)	3.517 (0.1410)	3.642 (0.1384)
95% C.I.	(3.240, 3.794)	(3.370, 3.914)
LS Mean Change from Baseline (SE)	-2.014 (0.1468)	-1.853 (0.1438)
95% C.I.	(-2.302, -1.726)	(-2.136, -1.571)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.161 (0.2055)
95% C.I.		(-0.243, 0.564)
Corrected Hedge’s g (SE) [3]		0.152 (0.1964)
95% C.I.		(-0.233, 0.537)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 15

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	57	62
n [2]	49	48
LS Mean (SE)	3.160 (0.1003)	3.197 (0.0993)
95% C.I.	(2.963, 3.357)	(3.002, 3.392)
LS Mean Change from Baseline (SE)	-2.372 (0.1136)	-2.300 (0.1114)
95% C.I.	(-2.595, -2.149)	(-2.518, -2.081)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.072 (0.1592)
95% C.I.		(-0.241, 0.384)
Corrected Hedge’s g (SE) [3]		0.091 (0.2032)
95% C.I.		(-0.307, 0.489)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 22

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	57	62
n [2]	48	53
LS Mean (SE)	3.068 (0.0630)	3.019 (0.0599)
95% C.I.	(2.945, 3.192)	(2.901, 3.136)
LS Mean Change from Baseline (SE)	-2.462 (0.0905)	-2.461 (0.0856)
95% C.I.	(-2.640, -2.285)	(-2.629, -2.293)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.002 (0.1246)
95% C.I.		(-0.243, 0.246)
Corrected Hedge’s g (SE) [3]		0.003 (0.1993)
95% C.I.		(-0.388, 0.393)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	57	62
n [2]	50	52
LS Mean (SE)	2.995 (0.0518)	2.968 (0.0503)
95% C.I.	(2.893, 3.096)	(2.869, 3.067)
LS Mean Change from Baseline (SE)	-2.527 (0.0869)	-2.507 (0.0831)
95% C.I.	(-2.697, -2.356)	(-2.670, -2.344)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.020 (0.1203)
95% C.I.		(-0.217, 0.256)
Corrected Hedge’s g (SE) [3]		0.032 (0.1981)
95% C.I.		(-0.356, 0.420)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 5

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	62	77
n [1]	59	76
n [2]	52	71
LS Mean (SE)	5.276 (0.1800)	4.447 (0.1547)
95% C.I.	(4.922, 5.629)	(4.144, 4.751)
LS Mean Change from Baseline (SE)	-1.272 (0.1752)	-2.023 (0.1505)
95% C.I.	(-1.616, -0.928)	(-2.318, -1.727)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.751 (0.2309)
95% C.I.		(-1.204, -0.297)
Corrected Hedge’s g (SE) [3]		-0.589 (0.1863)
95% C.I.		(-0.954, -0.224)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 8

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	59	76
n [2]	50	65
LS Mean (SE)	4.176 (0.1551)	3.746 (0.1354)
95% C.I.	(3.871, 4.481)	(3.480, 4.011)
LS Mean Change from Baseline (SE)	-2.370 (0.1537)	-2.725 (0.1341)
95% C.I.	(-2.672, -2.068)	(-2.988, -2.462)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.355 (0.2040)
95% C.I.		(-0.756, 0.045)
Corrected Hedge’s g (SE) [3]		-0.326 (0.1893)
95% C.I.		(-0.697, 0.045)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 11

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	59	76
n [2]	46	62
LS Mean (SE)	3.607 (0.1455)	3.551 (0.1259)
95% C.I.	(3.321, 3.893)	(3.304, 3.798)
LS Mean Change from Baseline (SE)	-2.933 (0.1510)	-2.924 (0.1307)
95% C.I.	(-3.229, -2.636)	(-3.181, -2.667)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.009 (0.1997)
95% C.I.		(-0.383, 0.401)
Corrected Hedge’s g (SE) [3]		0.009 (0.1946)
95% C.I.		(-0.373, 0.390)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 15

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	59	76
n [2]	49	64
LS Mean (SE)	3.465 (0.0997)	3.159 (0.0873)
95% C.I.	(3.269, 3.660)	(2.987, 3.330)
LS Mean Change from Baseline (SE)	-3.074 (0.1127)	-3.316 (0.0984)
95% C.I.	(-3.295, -2.853)	(-3.509, -3.123)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.242 (0.1495)
95% C.I.		(-0.536, 0.052)
Corrected Hedge’s g (SE) [3]		-0.305 (0.1909)
95% C.I.		(-0.679, 0.069)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 22

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	59	76
n [2]	43	64
LS Mean (SE)	3.109 (0.0651)	3.036 (0.0543)
95% C.I.	(2.981, 3.236)	(2.929, 3.142)
LS Mean Change from Baseline (SE)	-3.424 (0.0914)	-3.435 (0.0771)
95% C.I.	(-3.604, -3.245)	(-3.587, -3.284)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.011 (0.1196)
95% C.I.		(-0.245, 0.224)
Corrected Hedge’s g (SE) [3]		-0.017 (0.1972)
95% C.I.		(-0.404, 0.369)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	59	76
n [2]	48	65
LS Mean (SE)	2.998 (0.0523)	3.025 (0.0449)
95% C.I.	(2.896, 3.101)	(2.937, 3.113)
LS Mean Change from Baseline (SE)	-3.530 (0.0868)	-3.445 (0.0744)
95% C.I.	(-3.700, -3.360)	(-3.591, -3.299)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.085 (0.1142)
95% C.I.		(-0.139, 0.310)
Corrected Hedge’s g (SE) [3]		0.141 (0.1905)
95% C.I.		(-0.232, 0.515)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 5

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	187	166
n [1]	179	164
n [2]	163	150
LS Mean (SE)	6.105 (0.1018)	5.613 (0.1061)
95% C.I.	(5.905, 6.305)	(5.405, 5.822)
LS Mean Change from Baseline (SE)	-2.002 (0.0991)	-2.468 (0.1033)
95% C.I.	(-2.197, -1.808)	(-2.671, -2.266)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.466 (0.1430)
95% C.I.		(-0.747, -0.185)
Corrected Hedge’s g (SE) [3]		-0.368 (0.1141)
95% C.I.		(-0.591, -0.144)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 8

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	179	164
n [2]	164	150
LS Mean (SE)	4.859 (0.0869)	4.487 (0.0905)
95% C.I.	(4.688, 5.029)	(4.310, 4.665)
LS Mean Change from Baseline (SE)	-3.255 (0.0860)	-3.587 (0.0898)
95% C.I.	(-3.424, -3.086)	(-3.764, -3.411)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.333 (0.1242)
95% C.I.		(-0.577, -0.089)
Corrected Hedge’s g (SE) [3]		-0.302 (0.1136)
95% C.I.		(-0.524, -0.079)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 11

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	179	164
n [2]	158	149
LS Mean (SE)	4.301 (0.0804)	4.036 (0.0831)
95% C.I.	(4.143, 4.459)	(3.873, 4.200)
LS Mean Change from Baseline (SE)	-3.807 (0.0837)	-4.037 (0.0866)
95% C.I.	(-3.971, -3.642)	(-4.207, -3.867)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.231 (0.1203)
95% C.I.		(-0.467, 0.005)
Corrected Hedge’s g (SE) [3]		-0.218 (0.1145)
95% C.I.		(-0.443, 0.006)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 15

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	179	164
n [2]	139	140
LS Mean (SE)	3.653 (0.0585)	3.633 (0.0592)
95% C.I.	(3.538, 3.768)	(3.517, 3.749)
LS Mean Change from Baseline (SE)	-4.457 (0.0657)	-4.441 (0.0670)
95% C.I.	(-4.586, -4.328)	(-4.573, -4.310)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.016 (0.0937)
95% C.I.		(-0.168, 0.200)
Corrected Hedge’s g (SE) [3]		0.020 (0.1197)
95% C.I.		(-0.215, 0.255)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 22

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	179	164
n [2]	146	139
LS Mean (SE)	3.344 (0.0359)	3.159 (0.0370)
95% C.I.	(3.274, 3.415)	(3.086, 3.231)
LS Mean Change from Baseline (SE)	-4.761 (0.0511)	-4.912 (0.0530)
95% C.I.	(-4.862, -4.661)	(-5.017, -4.808)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.151 (0.0735)
95% C.I.		(-0.296, -0.007)
Corrected Hedge’s g (SE) [3]		-0.243 (0.1189)
95% C.I.		(-0.476, -0.010)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.22
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) by Visit and Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
n [1]	179	164
n [2]	153	138
LS Mean (SE)	3.139 (0.0294)	3.090 (0.0310)
95% C.I.	(3.081, 3.197)	(3.030, 3.151)
LS Mean Change from Baseline (SE)	-4.948 (0.0490)	-4.985 (0.0514)
95% C.I.	(-5.044, -4.852)	(-5.086, -4.884)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.037 (0.0708)
95% C.I.		(-0.176, 0.102)
Corrected Hedge’s g (SE) [3]		-0.061 (0.1174)
95% C.I.		(-0.291, 0.170)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the current time point.
[3] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an MMRM model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7), visit, week 24 baseline viral load by visit, treatment by visit, treatment by week 24 baseline viral load, visit by week 24 baseline viral load and treatment by visit by week 24 baseline viral load interactions.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Protocol: 214367
Population: Week 24 Virology

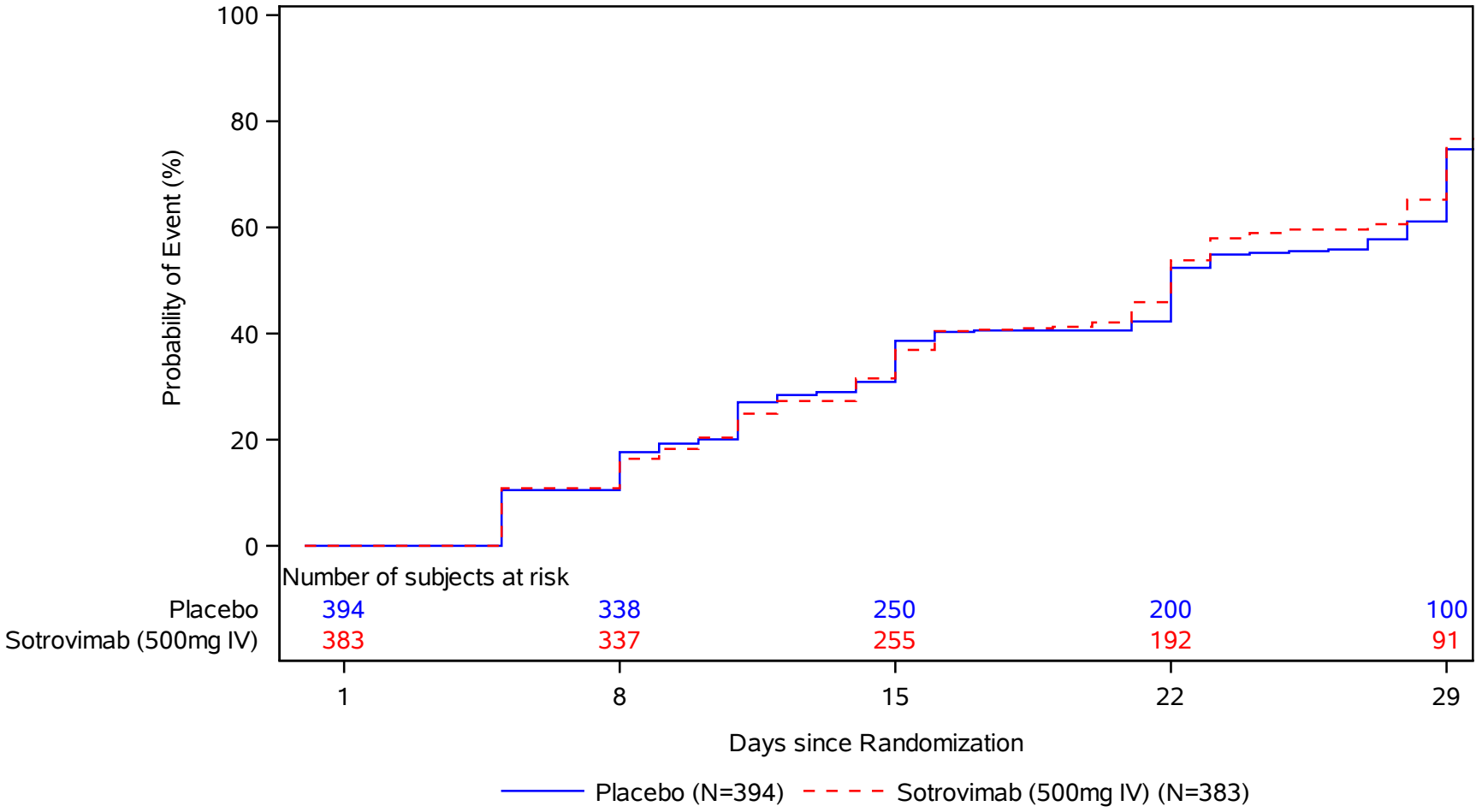
Table 212.23
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Negative SARS-CoV-2 viral load	263 (67%)	275 (72%)
Censored	131 (33%)	108 (28%)
75th Percentile (95% C.I.)	30 (29,31)	29 (29,30)
Median (95% C.I.)	22 (22,24)	22 (21,23)
25th Percentile (95% C.I.)	11 (11,14)	12 (11,14)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.94
95% C.I.		(0.79, 1.11)
p-value		0.443

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with a covariate of treatment.
Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.
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Figure 212.2
Kaplan-Meier Plot of Time to Negative Nasal SARS-CoV-2 PCR Test



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Table 212.24
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Age Group (<=70, >70)

Age group (years): <=70

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
	Number of subjects in subgroup		345	339
Day 8	Viral Load (log10 copies/mL)	n	294	291
		Mean	4.166	3.940
		SD	1.2856	1.1309
		Median	3.746	3.515
		Min.	2.873	2.873
		Max.	7.825	8.231
	Change from Baseline (log10 copies/mL)	n	294	291
		Mean	-2.497	-2.605
		SD	1.4075	1.4049
		Median	-2.456	-2.633
		Min.	-5.875	-5.981
		Max.	2.576	1.558

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

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Table 212.24
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Age Group (<=70, >70)

Age group (years): >70

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
	Number of subjects in subgroup		49	44
Day 8	Viral Load (log10 copies/mL)	n	44	42
		Mean	5.030	4.395
		SD	1.6539	1.5669
		Median	4.838	3.811
		Min.	2.873	2.873
		Max.	8.416	7.964
	Change from Baseline (log10 copies/mL)	n	44	42
		Mean	-1.782	-2.710
		SD	1.9891	1.8310
		Median	-1.992	-3.147
		Min.	-5.090	-5.238
		Max.	4.615	2.328

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

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Protocol: 214367
Population: Week 24 Virology

Table 212.25
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Age Group (<=70, >70)

Age group (years): <=70

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	345	339
n	294	291
LS Mean (SE)	4.163 (0.0634)	3.976 (0.0638)
95% C.I.	(4.038, 4.287)	(3.850, 4.101)
LS Mean Change from Baseline (SE)	-2.486 (0.0634)	-2.673 (0.0638)
95% C.I.	(-2.611, -2.362)	(-2.799, -2.548)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.187 (0.0900)
95% C.I.		(-0.364, -0.011)
p-value		0.038
Corrected Hedge’s g (SE) [1]		-0.172 (0.0828)
95% C.I.		(-0.334, -0.010)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline and treatment by age interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Table 212.25
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Age Group (<=70, >70)

Age group (years): >70

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	49	44
n	44	42
LS Mean (SE)	4.964 (0.1639)	4.237 (0.1682)
95% C.I.	(4.642, 5.285)	(3.906, 4.567)
LS Mean Change from Baseline (SE)	-1.685 (0.1639)	-2.412 (0.1682)
95% C.I.	(-2.007, -1.364)	(-2.743, -2.082)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.727 (0.2346)
95% C.I.		(-1.188, -0.266)
p-value		0.003
Corrected Hedge’s g (SE) [1]		-0.662 (0.2216)
95% C.I.		(-1.096, -0.228)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline and treatment by age interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Protocol: 214367
Population: Week 24 Virology

Table 212.26
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29
by Age Group (<=70, >70)

Age group (years): <=70

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	345	339
Negative SARS-CoV-2 viral load	236 (68%)	247 (73%)
Censored	109 (32%)	92 (27%)
75th Percentile (95% C.I.)	29 (29,30)	29 (29,30)
Median (95% C.I.)	22 (21,23)	22 (21,23)
25th Percentile (95% C.I.)	11 (9,12)	11 (10,14)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.97
95% C.I.		(0.81, 1.16)
p-value		0.772

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, age (<=70, >70 years old) and treatment by age interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.

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Protocol: 214367
Population: Week 24 Virology

Table 212.26
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29
by Age Group (<=70, >70)

Age group (years): >70

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	49	44
Negative SARS-CoV-2 viral load	27 (55%)	28 (64%)
Censored	22 (45%)	16 (36%)
75th Percentile (95% C.I.)	33 (29,NE)	32 (29,32)
Median (95% C.I.)	29 (22,33)	22 (15,29)
25th Percentile (95% C.I.)	21 (12,24)	12 (8,17)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.73
95% C.I.		(0.43, 1.24)
p-value		0.244

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, age (<=70, >70 years old) and treatment by age interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.
PPD

Protocol: 214367
Population: Week 24 Virology

Table 212.27
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
	Number of subjects in subgroup		87	76
Day 8	Viral Load (log10 copies/mL)	n	74	60
		Mean	3.385	3.140
		SD	1.0131	0.4772
		Median	2.873	2.873
		Min.	2.873	2.873
		Max.	8.416	5.073
	Change from Baseline (log10 copies/mL)	n	74	60
		Mean	-0.924	-1.002
		SD	1.0968	0.5967
		Median	-1.111	-0.931
		Min.	-2.118	-2.076
		Max.	4.615	0.426

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 212.27
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
	Number of subjects in subgroup		58	64
Day 8	Viral Load (log10 copies/mL)	n	50	58
		Mean	3.792	3.741
		SD	1.2838	1.2231
		Median	3.270	3.270
		Min.	2.873	2.873
		Max.	7.927	7.879
	Change from Baseline (log10 copies/mL)	n	50	58
		Mean	-1.777	-1.731
		SD	1.2667	1.1843
		Median	-2.295	-2.127
		Min.	-3.099	-3.042
		Max.	2.736	2.328

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 212.27
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
	Number of subjects in subgroup		62	77
Day 8	Viral Load (log10 copies/mL)	n	50	65
		Mean	4.172	3.756
		SD	1.1463	1.0077
		Median	3.986	3.270
		Min.	2.873	2.873
		Max.	7.165	7.877
	Change from Baseline (log10 copies/mL)	n	50	65
		Mean	-2.356	-2.732
		SD	1.1806	1.0505
		Median	-2.438	-3.000
		Min.	-3.997	-4.055
		Max.	0.517	1.653

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 212.27
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
	Number of subjects in subgroup		187	166
Day 8	Viral Load (log10 copies/mL)	n	164	150
		Mean	4.862	4.543
		SD	1.3176	1.2125
		Median	4.726	4.438
		Min.	2.873	2.873
		Max.	7.825	8.231
	Change from Baseline (log10 copies/mL)	n	164	150
		Mean	-3.278	-3.558
		SD	1.1836	1.1669
		Median	-3.416	-3.750
		Min.	-5.875	-5.981
		Max.	-0.169	-0.220

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Population: Week 24 Virology

Table 212.28
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	87	76
n	74	60
LS Mean (SE)	3.430 (0.1313)	3.189 (0.1460)
95% C.I.	(3.172, 3.687)	(2.902, 3.476)
LS Mean Change from Baseline (SE)	-0.899 (0.1297)	-0.975 (0.1442)
95% C.I.	(-1.154, -0.644)	(-1.258, -0.692)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.076 (0.1936)
95% C.I.		(-0.456, 0.304)
p-value		0.695
Corrected Hedge’s g (SE) [1]		-0.068 (0.1738)
95% C.I.		(-0.408, 0.273)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Table 212.28
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	58	64
n	50	58
LS Mean (SE)	3.790 (0.1597)	3.825 (0.1486)
95% C.I.	(3.477, 4.104)	(3.533, 4.117)
LS Mean Change from Baseline (SE)	-1.777 (0.1578)	-1.680 (0.1468)
95% C.I.	(-2.087, -1.467)	(-1.968, -1.392)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.097 (0.2154)
95% C.I.		(-0.326, 0.520)
p-value		0.654
Corrected Hedge’s g (SE) [1]		0.086 (0.1931)
95% C.I.		(-0.292, 0.465)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction. Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.28
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	62	77
n	50	65
LS Mean (SE)	4.193 (0.1596)	3.748 (0.1398)
95% C.I.	(3.880, 4.507)	(3.474, 4.023)
LS Mean Change from Baseline (SE)	-2.349 (0.1577)	-2.739 (0.1381)
95% C.I.	(-2.659, -2.040)	(-3.010, -2.468)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.390 (0.2096)
95% C.I.		(-0.801, 0.022)
p-value		0.064
Corrected Hedge’s g (SE) [1]		-0.347 (0.1895)
95% C.I.		(-0.719, 0.024)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.28
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	187	166
n	164	150
LS Mean (SE)	4.838 (0.0881)	4.492 (0.0928)
95% C.I.	(4.665, 5.011)	(4.310, 4.675)
LS Mean Change from Baseline (SE)	-3.291 (0.0870)	-3.585 (0.0917)
95% C.I.	(-3.462, -3.121)	(-3.765, -3.405)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.294 (0.1260)
95% C.I.		(-0.541, -0.046)
p-value		0.020
Corrected Hedge’s g (SE) [1]		-0.262 (0.1135)
95% C.I.		(-0.485, -0.040)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Protocol: 214367
Population: Week 24 Virology

Table 212.29
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	87	76
Negative SARS-CoV-2 viral load	81 (93%)	71 (93%)
Censored	6 (7%)	5 (7%)
75th Percentile (95% C.I.)	21 (15,24)	19 (12,23)
Median (95% C.I.)	11 (8,13)	10 (8,11)
25th Percentile (95% C.I.)	5 (5,8)	5 (5,8)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.96
95% C.I.		(0.69, 1.32)
p-value		0.794

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.

PPD

Population: Week 24 Virology

Table 212.29
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	58	64
Negative SARS-CoV-2 viral load	43 (74%)	48 (75%)
Censored	15 (26%)	16 (25%)
75th Percentile (95% C.I.)	28 (22,NE)	28 (22,30)
Median (95% C.I.)	15 (9,22)	17 (14,22)
25th Percentile (95% C.I.)	8 (5,9)	8 (5,14)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		1.03
95% C.I.		(0.68, 1.56)
p-value		0.878

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.

PPD

Population: Week 24 Virology

Table 212.29
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	62	77
Negative SARS-CoV-2 viral load	40 (65%)	58 (75%)
Censored	22 (35%)	19 (25%)
75th Percentile (95% C.I.)	29 (28,31)	29 (25,NE)
Median (95% C.I.)	22 (15,28)	19 (15,23)
25th Percentile (95% C.I.)	12 (10,15)	12 (10,15)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.97
95% C.I.		(0.65, 1.45)
p-value		0.868

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.

PPD

Table 212.29
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	187	166
Negative SARS-CoV-2 viral load	99 (53%)	98 (59%)
Censored	88 (47%)	68 (41%)
75th Percentile (95% C.I.)	41 (30,41)	31 (30,32)
Median (95% C.I.)	29 (NE,NE)	29 (27,29)
25th Percentile (95% C.I.)	22 (16,22)	21 (20,22)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.88
95% C.I.		(0.67, 1.17)
p-value		0.385

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.

PPD

Protocol: 214367
Population: Week 24 Virology

Table 212.30
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Gender

Gender: Male

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
	Number of subjects in subgroup		197	182
Day 8	Viral Load (log10 copies/mL)	n	172	159
		Mean	4.325	4.034
		SD	1.4271	1.2608
		Median	3.794	3.449
		Min.	2.873	2.873
		Max.	7.825	8.231
	Change from Baseline (log10 copies/mL)	n	172	159
		Mean	-2.367	-2.535
		SD	1.5121	1.5039
		Median	-2.452	-2.521
		Min.	-5.875	-5.499
		Max.	2.576	2.328

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 212.30
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Gender

Gender: Female

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
	Number of subjects in subgroup		197	201
Day 8	Viral Load (log10 copies/mL)	n	166	174
		Mean	4.230	3.963
		SD	1.3061	1.1470
		Median	3.947	3.578
		Min.	2.873	2.873
		Max.	8.416	7.964
	Change from Baseline (log10 copies/mL)	n	166	174
		Mean	-2.443	-2.694
		SD	1.5150	1.4240
		Median	-2.394	-2.868
		Min.	-5.184	-5.981
		Max.	4.615	1.794

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Protocol: 214367
Population: Week 24 Virology

Table 212.31
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Gender

Gender: Male

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	197	182
n	172	159
LS Mean (SE)	4.305 (0.0832)	4.070 (0.0865)
95% C.I.	(4.141, 4.468)	(3.900, 4.240)
LS Mean Change from Baseline (SE)	-2.344 (0.0832)	-2.579 (0.0865)
95% C.I.	(-2.508, -2.181)	(-2.749, -2.409)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.235 (0.1201)
95% C.I.		(-0.470, 0.001)
p-value		0.052
Corrected Hedge’s g (SE) [1]		-0.215 (0.1103)
95% C.I.		(-0.431, 0.002)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline and treatment by gender interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.31
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Gender

Gender: Female

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	197	201
n	166	174
LS Mean (SE)	4.229 (0.0848)	3.951 (0.0827)
95% C.I.	(4.063, 4.396)	(3.789, 4.114)
LS Mean Change from Baseline (SE)	-2.420 (0.0848)	-2.698 (0.0827)
95% C.I.	(-2.586, -2.253)	(-2.860, -2.535)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.278 (0.1187)
95% C.I.		(-0.511, -0.045)
p-value		0.020
Corrected Hedge’s g (SE) [1]		-0.254 (0.1089)
95% C.I.		(-0.468, -0.041)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline and treatment by gender interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Protocol: 214367
Population: Week 24 Virology

Table 212.32
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Gender

Gender: Male

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	197	182
Negative SARS-CoV-2 viral load	127 (64%)	134 (74%)
Censored	70 (36%)	48 (26%)
75th Percentile (95% C.I.)	30 (29,41)	29 (28,31)
Median (95% C.I.)	22 (22,27)	21 (16,22)
25th Percentile (95% C.I.)	11 (10,15)	11 (10,14)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.82
95% C.I.		(0.65, 1.05)
p-value		0.121

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, gender (male, female) and treatment by gender interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.

PPD

Population: Week 24 Virology

Table 212.32
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Gender

Gender: Female

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	197	201
Negative SARS-CoV-2 viral load	136 (69%)	141 (70%)
Censored	61 (31%)	60 (30%)
75th Percentile (95% C.I.)	29 (29,31)	29 (29,32)
Median (95% C.I.)	22 (21,28)	23 (22,28)
25th Percentile (95% C.I.)	11 (8,14)	14 (10,15)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		1.05
95% C.I.		(0.83, 1.33)
p-value		0.684

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, gender (male, female) and treatment by gender interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.

PPD

Protocol: 214367
Population: Week 24 Virology

Table 212.33
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Number of Risk Factors

Number of risk factors: <=1

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
	Number of subjects in subgroup		225	213
Day 8	Viral Load (log10 copies/mL)	n	194	186
		Mean	4.263	3.972
		SD	1.3489	1.1259
		Median	3.910	3.519
		Min.	2.873	2.873
		Max.	7.927	7.879
	Change from Baseline (log10 copies/mL)	n	194	186
		Mean	-2.479	-2.643
		SD	1.5353	1.4541
		Median	-2.511	-2.686
		Min.	-5.210	-5.981
		Max.	2.736	2.328

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 212.33
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Number of Risk Factors

Number of risk factors: 2

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
	Number of subjects in subgroup		117	129
Day 8	Viral Load (log10 copies/mL)	n	103	114
		Mean	4.272	4.041
		SD	1.3825	1.2964
		Median	3.890	3.595
		Min.	2.873	2.873
		Max.	8.416	8.231
	Change from Baseline (log10 copies/mL)	n	103	114
		Mean	-2.309	-2.491
		SD	1.5736	1.4685
		Median	-2.303	-2.658
		Min.	-5.875	-5.117
		Max.	4.615	1.794

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

Table 212.33
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Number of Risk Factors

Number of risk factors: >=3

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
	Number of subjects in subgroup		52	41
Day 8	Viral Load (log10 copies/mL)	n	41	33
		Mean	4.366	3.987
		SD	1.4489	1.3037
		Median	4.016	3.360
		Min.	2.873	2.873
		Max.	7.796	7.964
	Change from Baseline (log10 copies/mL)	n	41	33
		Mean	-2.289	-2.914
		SD	1.2266	1.4843
		Median	-2.389	-2.952
		Min.	-4.554	-5.313
		Max.	-0.163	0.091

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Protocol: 214367
Population: Week 24 Virology

Table 212.34
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Number of Risk Factors

Number of risk factors: <=1

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	225	213
n	194	186
LS Mean (SE)	4.239 (0.0784)	4.005 (0.0803)
95% C.I.	(4.085, 4.393)	(3.847, 4.162)
LS Mean Change from Baseline (SE)	-2.410 (0.0784)	-2.644 (0.0803)
95% C.I.	(-2.564, -2.256)	(-2.802, -2.487)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.234 (0.1121)
95% C.I.		(-0.454, -0.014)
p-value		0.038
Corrected Hedge’s g (SE) [1]		-0.213 (0.1029)
95% C.I.		(-0.415, -0.012)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.34
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Number of Risk Factors

Number of risk factors: 2

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	117	129
n	103	114
LS Mean (SE)	4.289 (0.1082)	4.074 (0.1025)
95% C.I.	(4.077, 4.501)	(3.873, 4.275)
LS Mean Change from Baseline (SE)	-2.360 (0.1082)	-2.575 (0.1025)
95% C.I.	(-2.572, -2.148)	(-2.776, -2.374)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.215 (0.1487)
95% C.I.		(-0.507, 0.077)
p-value		0.149
Corrected Hedge’s g (SE) [1]		-0.196 (0.1363)
95% C.I.		(-0.463, 0.071)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.34
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Number of Risk Factors

Number of risk factors: >=3

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	52	41
n	41	33
LS Mean (SE)	4.340 (0.1708)	3.812 (0.1917)
95% C.I.	(4.005, 4.675)	(3.436, 4.188)
LS Mean Change from Baseline (SE)	-2.309 (0.1708)	-2.837 (0.1917)
95% C.I.	(-2.644, -1.974)	(-3.214, -2.461)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.528 (0.2558)
95% C.I.		(-1.030, -0.026)
p-value		0.040
Corrected Hedge’s g (SE) [1]		-0.476 (0.2371)
95% C.I.		(-0.941, -0.012)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.35
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29
by Number of Risk Factors

Number of risk factors: <=1

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	225	213
Negative SARS-CoV-2 viral load	151 (67%)	147 (69%)
Censored	74 (33%)	66 (31%)
75th Percentile (95% C.I.)	29 (29,NE)	30 (29,32)
Median (95% C.I.)	22 (22,27)	22 (21,25)
25th Percentile (95% C.I.)	11 (9,15)	12 (11,15)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		1.00
95% C.I.		(0.80, 1.26)
p-value		0.969

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.

PPD

Population: Week 24 Virology

Table 212.35
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29
by Number of Risk Factors

Number of risk factors: 2

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	117	129
Negative SARS-CoV-2 viral load	77 (66%)	97 (75%)
Censored	40 (34%)	32 (25%)
75th Percentile (95% C.I.)	31 (29,41)	29 (29,30)
Median (95% C.I.)	22 (16,28)	22 (21,25)
25th Percentile (95% C.I.)	12 (9,15)	11 (9,15)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.90
95% C.I.		(0.66, 1.21)
p-value		0.475

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.

PPD

Table 212.35
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29
by Number of Risk Factors

Number of risk factors: >=3

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	52	41
Negative SARS-CoV-2 viral load	35 (67%)	31 (76%)
Censored	17 (33%)	10 (24%)
75th Percentile (95% C.I.)	30 (28,NE)	27 (22,NE)
Median (95% C.I.)	22 (15,29)	20 (11,22)
25th Percentile (95% C.I.)	11 (5,15)	9 (5,14)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.70
95% C.I.		(0.43, 1.14)
p-value		0.158

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, number of risk factors (<=1, 2, >=3) and treatment by number of risk factors interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.

PPD

Protocol: 214367
Population: Week 24 Virology

Table 212.36
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
	Number of subjects in subgroup		174	178
Day 8	Viral Load (log10 copies/mL)	n	150	154
		Mean	4.212	4.088
		SD	1.4060	1.2949
		Median	3.716	3.599
		Min.	2.873	2.873
		Max.	8.416	8.231
	Change from Baseline (log10 copies/mL)	n	150	154
		Mean	-2.379	-2.529
		SD	1.5414	1.4573
		Median	-2.418	-2.555
		Min.	-5.276	-5.499
		Max.	4.615	2.328

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 212.36
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
	Number of subjects in subgroup		160	156
Day 8	Viral Load (log10 copies/mL)	n	142	138
		Mean	4.298	3.882
		SD	1.3408	1.0969
		Median	3.985	3.499
		Min.	2.873	2.873
		Max.	7.825	7.964
	Change from Baseline (log10 copies/mL)	n	142	138
		Mean	-2.396	-2.748
		SD	1.5307	1.4609
		Median	-2.367	-2.948
		Min.	-5.184	-5.981
		Max.	2.576	1.653

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Protocol: 214367
Population: Week 24 Virology

Table 212.37
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	174	178
n	150	154
LS Mean (SE)	4.204 (0.0903)	4.064 (0.0889)
95% C.I.	(4.027, 4.382)	(3.889, 4.238)
LS Mean Change from Baseline (SE)	-2.428 (0.0903)	-2.569 (0.0889)
95% C.I.	(-2.605, -2.251)	(-2.743, -2.394)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.141 (0.1263)
95% C.I.		(-0.389, 0.107)
p-value		0.266
Corrected Hedge’s g (SE) [1]		-0.127 (0.1148)
95% C.I.		(-0.352, 0.098)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.37
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	160	156
n	142	138
LS Mean (SE)	4.300 (0.0927)	3.916 (0.0941)
95% C.I.	(4.118, 4.483)	(3.731, 4.101)
LS Mean Change from Baseline (SE)	-2.332 (0.0927)	-2.716 (0.0941)
95% C.I.	(-2.514, -2.150)	(-2.901, -2.531)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.384 (0.1317)
95% C.I.		(-0.643, -0.126)
p-value		0.004
Corrected Hedge’s g (SE) [1]		-0.347 (0.1204)
95% C.I.		(-0.583, -0.111)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Protocol: 214367
Population: Week 24 Virology

Table 212.38
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29
by Patient Reported Symptom Severity

Patient reported symptom severity: <2 moderate/higher intensity

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	174	178
Negative SARS-CoV-2 viral load	108 (62%)	129 (72%)
Censored	66 (38%)	49 (28%)
75th Percentile (95% C.I.)	NE (29,NE)	29 (29,30)
Median (95% C.I.)	22 (22,27)	22 (16,23)
25th Percentile (95% C.I.)	11 (8,11)	11 (9,12)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.83
95% C.I.		(0.64, 1.07)
p-value		0.142

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.

PPD

Table 212.38
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29
by Patient Reported Symptom Severity

Patient reported symptom severity: >=2 moderate/higher intensity

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	160	156
Negative SARS-CoV-2 viral load	116 (73%)	116 (74%)
Censored	44 (28%)	40 (26%)
75th Percentile (95% C.I.)	29 (29,30)	29 (28,31)
Median (95% C.I.)	22 (22,27)	22 (16,24)
25th Percentile (95% C.I.)	14 (11,15)	14 (9,15)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.96
95% C.I.		(0.74, 1.24)
p-value		0.767

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, patient reported symptom severity (<2, >=2) and treatment by patient reported symptom severity interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.

PPD

Population: Week 24 Virology

Table 212.39
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Region

Region: Europe

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
	Number of subjects in subgroup		14	13
Day 8	Viral Load (log10 copies/mL)	n	12	13
		Mean	5.372	5.040
		SD	1.3719	1.1446
		Median	5.885	4.844
		Min.	3.270	3.270
		Max.	7.632	6.823
	Change from Baseline (log10 copies/mL)	n	12	13
		Mean	-2.416	-2.862
		SD	1.2529	1.3138
		Median	-2.647	-2.683
		Min.	-4.007	-5.313
		Max.	-0.152	-0.363

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 212.39
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Region

Region: North America

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
	Number of subjects in subgroup		369	359
Day 8	Viral Load (log10 copies/mL)	n	318	310
		Mean	4.215	3.932
		SD	1.3530	1.1787
		Median	3.794	3.453
		Min.	2.873	2.873
		Max.	8.416	8.231
	Change from Baseline (log10 copies/mL)	n	318	310
		Mean	-2.393	-2.604
		SD	1.5313	1.4712
		Median	-2.394	-2.725
		Min.	-5.875	-5.981
		Max.	4.615	2.328

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Table 212.39
Summary of Absolute and Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Region

Region: South America

Visit			Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
	Number of subjects in subgroup		11	11
Day 8	Viral Load (log10 copies/mL)	n	8	10
		Mean	5.148	4.647
		SD	1.0552	1.2688
		Median	5.467	4.305
		Min.	3.270	2.873
		Max.	6.581	6.865
	Change from Baseline (log10 copies/mL)	n	8	10
		Mean	-2.827	-2.744
		SD	1.0801	1.4783
		Median	-3.139	-2.965
		Min.	-4.359	-4.402
		Max.	-0.575	0.426

Note: Values <lower limit of detection (LLD=1493 copies/mL) are imputed to 0.5*LLD, detectable values <lower limit of quantification (LLQ=2228 copies/mL) are imputed to LLQ-0.5*(LLQ-LLD) prior to taking the log 10 value.

PPD

Protocol: 214367
Population: Week 24 Virology

Table 212.40
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Region

Region: Europe

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	14	13
n	12	13
LS Mean (SE)	4.922 (0.3163)	4.588 (0.3054)
95% C.I.	(4.301, 5.544)	(3.989, 5.188)
LS Mean Change from Baseline (SE)	-1.727 (0.3163)	-2.061 (0.3054)
95% C.I.	(-2.348, -1.106)	(-2.661, -1.461)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.334 (0.4375)
95% C.I.		(-1.193, 0.525)
p-value		0.446
Corrected Hedge’s g (SE) [1]		-0.294 (0.4025)
95% C.I.		(-1.083, 0.495)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline and treatment by region interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.40
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Region

Region: North America

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	369	359
n	318	310
LS Mean (SE)	4.229 (0.0612)	3.975 (0.0620)
95% C.I.	(4.109, 4.349)	(3.853, 4.097)
LS Mean Change from Baseline (SE)	-2.420 (0.0612)	-2.674 (0.0620)
95% C.I.	(-2.540, -2.300)	(-2.796, -2.552)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.254 (0.0871)
95% C.I.		(-0.425, -0.083)
p-value		0.004
Corrected Hedge’s g (SE) [1]		-0.232 (0.0801)
95% C.I.		(-0.389, -0.075)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline and treatment by region interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Week 24 Virology

Table 212.40
Analysis of Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (log 10 copies/mL) at Day 8 by Region

Region: South America

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	11	11
n	8	10
LS Mean (SE)	4.657 (0.3891)	4.408 (0.3469)
95% C.I.	(3.893, 5.421)	(3.726, 5.089)
LS Mean Change from Baseline (SE)	-1.992 (0.3891)	-2.241 (0.3469)
95% C.I.	(-2.756, -1.228)	(-2.923, -1.560)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.249 (0.5181)
95% C.I.		(-1.267, 0.768)
p-value		0.631
Corrected Hedge’s g (SE) [1]		-0.216 (0.4757)
95% C.I.		(-1.148, 0.716)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, region (North America, Europe, South America), duration of symptoms (<=3 days, >=4 days), age (<=70, >70 years old), gender (male, female), baseline and treatment by region interaction.
Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Protocol: 214367
Population: Week 24 Virology

Table 212.41
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Region

Region: Europe

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	14	13
Negative SARS-CoV-2 viral load	3 (21%)	5 (38%)
Censored	11 (79%)	8 (62%)
75th Percentile (95% C.I.)	NE (NE,NE)	NE (29,NE)
Median (95% C.I.)	NE (29,NE)	NE (11,NE)
25th Percentile (95% C.I.)	29 (15,NE)	29 (11,NE)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.47
95% C.I.		(0.11, 1.97)
p-value		0.303

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, region (North America, Europe, South America) and treatment by region interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.
PPD

Population: Week 24 Virology

Table 212.41
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Region

Region: North America

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	369	359
Negative SARS-CoV-2 viral load	259 (70%)	266 (74%)
Censored	110 (30%)	93 (26%)
75th Percentile (95% C.I.)	29 (29,30)	29 (29,30)
Median (95% C.I.)	22 (21,22)	22 (21,22)
25th Percentile (95% C.I.)	11 (9,12)	11 (10,14)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.97
95% C.I.		(0.82, 1.15)
p-value		0.734

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, region (North America, Europe, South America) and treatment by region interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.
PPD

Population: Week 24 Virology

Table 212.41
Summary and Analysis of Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29 by Region

Region: South America

	Placebo (N=394)	Sotrovimab (500mg IV) (N=383)
Number of subjects in subgroup	11	11
Negative SARS-CoV-2 viral load	1 (9%)	4 (36%)
Censored	10 (91%)	7 (64%)
75th Percentile (95% C.I.)	NE (NE,NE)	NE (28,NE)
Median (95% C.I.)	NE (28,NE)	29 (21,NE)
25th Percentile (95% C.I.)	NE (28,NE)	28 (21,29)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.22
95% C.I.		(0.02, 1.94)
p-value		0.171

Note: Subjects without two consecutive negative results by Day 29 (or one negative result at Day 29) were censored at the latest non-missing viral load result.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, region (North America, Europe, South America) and treatment by region interaction term.
Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.

PPD

Population: Week 24 Virology

Table 212.42
P-values for Interactions of Treatment with Subgroups for Change from Week 24 Baseline in Nasal SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8

Interaction of Treatment with:	P-value [1]
Age group (<=70, >70 years old)	0.033
Week 24 Baseline SARS-CoV-2 viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.301
Gender (Female, Male)	0.798
Number of risk factors (<=1, 2, >=3)	0.538
Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.183
Region (North America, Europe, South America)	0.984

[1] Interaction p-values obtained from ANCOVA models with covariates of treatment, region (North America, Europe, South America), duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), baseline, subgroup (if not already in the model) and subgroup by treatment interaction.

PPD

Population: Week 24 Virology

Table 212.43
P-values for Interactions of Treatment with Subgroups for Time to Negative Nasal SARS-CoV-2 PCR Test by Day 29

Interaction of Treatment with:	P-value [1]
Age group (<=70, >70 years old)	0.311
Week 24 Baseline SARS-CoV-2 viral load (<=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.936
Gender (Female, Male)	0.162
Number of risk factors (<=1, 2, >=3)	0.416
Patient reported symptom severity (<2, >=2 moderate/higher intensity)	0.409
Region (North America, Europe, South America)	0.255

[1] Interaction p-values obtained from Cox proportional hazards models with covariates of treatment, subgroup and subgroup by treatment interaction.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 212.44
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		97	101
Day 8	Viral Load (log10 copies/mL)	n	16	11
		Mean	2.676	2.676
		SD	0.0000	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.676	2.676
	Change from Baseline (log10 copies/mL)	n	6	3
		Mean	0.000	0.000
		SD	0.0000	0.0000
		Median	0.000	0.000
		Min.	0.000	0.000
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.
PPD

Table 212.44
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		87	76
Day 8	Viral Load (log10 copies/mL)	n	7	9
		Mean	2.676	2.676
		SD	0.0000	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.676	2.676
	Change from Baseline (log10 copies/mL)	n	3	1
		Mean	0.000	0.000
		SD	0.0000	
		Median	0.000	0.000
		Min.	0.000	0.000
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Population: Intent-to-Treat

Table 212.44
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		58	64
Day 8	Viral Load (log10 copies/mL)	n	4	7
		Mean	2.826	2.676
		SD	0.1738	0.0000
		Median	2.826	2.676
		Min.	2.676	2.676
		Max.	2.977	2.676
	Change from Baseline (log10 copies/mL)	n	3	2
		Mean	-0.119	-0.301
		SD	0.2057	0.0000
		Median	0.000	-0.301
		Min.	-0.356	-0.301
		Max.	0.000	-0.301

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.

PPD

Population: Intent-to-Treat

Table 212.44
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		62	77
Day 8	Viral Load (log10 copies/mL)	n	8	7
		Mean	2.676	2.676
		SD	0.0000	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.676	2.676
	Change from Baseline (log10 copies/mL)	n	1	2
		Mean	0.000	0.000
		SD		0.0000
		Median	0.000	0.000
		Min.	0.000	0.000
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.
PPD

Population: Intent-to-Treat

Table 212.44
Summary of Absolute and Change from Baseline in Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		187	166
Day 8	Viral Load (log10 copies/mL)	n	14	22
		Mean	2.697	2.676
		SD	0.0805	0.0000
		Median	2.676	2.676
		Min.	2.676	2.676
		Max.	2.977	2.676
	Change from Baseline (log10 copies/mL)	n	4	11
		Mean	-0.075	-0.219
		SD	0.1505	0.1406
		Median	0.000	-0.301
		Min.	-0.301	-0.301
		Max.	0.000	0.000

Note: Undetectable blood viral load results are imputed to 0.5*lower limit of quantification (LLQ=948 copies/mL), detectable values <LLQ are imputed to LLQ prior to taking the log 10 value.
PPD

Population: Intent-to-Treat

Table 212.45
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
n	6	3
LS Mean (SE)	2.712 (0.0238)	2.712 (0.0325)
95% C.I.	(2.663, 2.761)	(2.645, 2.779)
LS Mean Change from Baseline (SE)	-0.082 (0.0238)	-0.082 (0.0325)
95% C.I.	(-0.131, -0.033)	(-0.149, -0.015)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.000 (0.0384)
95% C.I.		(-0.079, 0.079)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		0.000 (0.7071)
95% C.I.		(-1.386, 1.386)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline nasal SARS-CoV-2 viral load category, baseline blood SARS-CoV-2 viral load and treatment by week 24 baseline nasal SARS-CoV-2 viral load category interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Intent-to-Treat

Table 212.45
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
n	3	1
LS Mean (SE)	2.712 (0.0325)	2.712 (0.0550)
95% C.I.	(2.645, 2.779)	(2.599, 2.826)
LS Mean Change from Baseline (SE)	-0.082 (0.0325)	-0.082 (0.0550)
95% C.I.	(-0.149, -0.015)	(-0.195, 0.031)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.000 (0.0628)
95% C.I.		(-0.129, 0.129)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		0.000 (1.1547)
95% C.I.		(-2.263, 2.263)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline nasal SARS-CoV-2 viral load category, baseline blood SARS-CoV-2 viral load and treatment by week 24 baseline nasal SARS-CoV-2 viral load category interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Intent-to-Treat

Table 212.45
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
n	3	2
LS Mean (SE)	2.745 (0.0322)	2.620 (0.0406)
95% C.I.	(2.679, 2.812)	(2.536, 2.703)
LS Mean Change from Baseline (SE)	-0.049 (0.0322)	-0.175 (0.0406)
95% C.I.	(-0.115, 0.017)	(-0.258, -0.091)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.126 (0.0500)
95% C.I.		(-0.228, -0.023)
p-value		0.019
Corrected Hedge’s g (SE) [1]		-1.621 (1.0469)
95% C.I.		(-3.673, 0.431)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline nasal SARS-CoV-2 viral load category, baseline blood SARS-CoV-2 viral load and treatment by week 24 baseline nasal SARS-CoV-2 viral load category interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Intent-to-Treat

Table 212.45
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	62	77
n	1	2
LS Mean (SE)	2.712 (0.0550)	2.712 (0.0394)
95% C.I.	(2.599, 2.826)	(2.631, 2.793)
LS Mean Change from Baseline (SE)	-0.082 (0.0550)	-0.082 (0.0394)
95% C.I.	(-0.195, 0.031)	(-0.163, -0.001)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.000 (0.0666)
95% C.I.		(-0.137, 0.137)
p-value		>0.999
Corrected Hedge’s g (SE) [1]		0.000 (1.2247)
95% C.I.		(-2.400, 2.400)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline nasal SARS-CoV-2 viral load category, baseline blood SARS-CoV-2 viral load and treatment by week 24 baseline nasal SARS-CoV-2 viral load category interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Intent-to-Treat

Table 212.45
Analysis of Change from Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
n	4	11
LS Mean (SE)	2.741 (0.0273)	2.645 (0.0179)
95% C.I.	(2.685, 2.797)	(2.608, 2.682)
LS Mean Change from Baseline (SE)	-0.053 (0.0273)	-0.149 (0.0179)
95% C.I.	(-0.109, 0.003)	(-0.186, -0.113)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-0.096 (0.0321)
95% C.I.		(-0.162, -0.030)
p-value		0.007
Corrected Hedge’s g (SE) [1]		-1.555 (0.6492)
95% C.I.		(-2.827, -0.282)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline nasal SARS-CoV-2 viral load category, baseline blood SARS-CoV-2 viral load and treatment by week 24 baseline nasal SARS-CoV-2 viral load category interaction.
Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events.
PPD

Population: Intent-to-Treat

Table 212.46
P-values for Interactions of Treatment with Subgroups for Change from Week 24 Baseline of Blood SARS-CoV-2 Viral Load (Log 10 copies/mL) at Day 8

Interaction of Treatment with:	P-value [1]
Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.167

[1] Interaction p-values obtained from ANCOVA model, adjusting for treatment, baseline blood SARS-CoV-2 viral load, subgroup and subgroup by treatment interaction.

PPD

Population: Safety

Table 213.1
Summary and Analysis of Proportion of Subjects with Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	97	101
Any event	25 (25.8%)	24 (23.8%)
Odds Ratio		0.90
95% CI		(0.47, 1.71)
Relative Risk		0.92
95% CI		(0.57, 1.50)
Risk Difference (%)		-2.01
95% CI		(-14.04, 10.02)
p-value [1]		0.870

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.1
Summary and Analysis of Proportion of Subjects with Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	4 (4.1%)	4 (4.0%)
Odds Ratio		0.96
95% CI		(0.23, 3.95)
Relative Risk		0.96
95% CI		(0.25, 3.73)
Risk Difference (%)		-0.16
95% CI		(-5.65, 5.33)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.1
Summary and Analysis of Proportion of Subjects with Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	0	1 (1.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		0.99
95% CI		(-0.94, 2.92)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.1
Summary and Analysis of Proportion of Subjects with Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	87	76
Any event	18 (20.7%)	25 (32.9%)
Odds Ratio		1.88
95% CI		(0.93, 3.81)
Relative Risk		1.59
95% CI		(0.94, 2.68)
Risk Difference (%)		12.21
95% CI		(-1.36, 25.77)
p-value [1]		0.109

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.1
Summary and Analysis of Proportion of Subjects with Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	7 (8.0%)	5 (6.6%)
Odds Ratio		0.80
95% CI		(0.24, 2.65)
Relative Risk		0.82
95% CI		(0.27, 2.47)
Risk Difference (%)		-1.47
95% CI		(-9.45, 6.52)
p-value [1]		0.773

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.1
Summary and Analysis of Proportion of Subjects with Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	0	1 (1.3%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		1.32
95% CI		(-1.25, 3.88)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.1
Summary and Analysis of Proportion of Subjects with Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	18 (31.0%)	18 (28.1%)
Odds Ratio		0.87
95% CI		(0.40, 1.89)
Relative Risk		0.91
95% CI		(0.52, 1.57)
Risk Difference (%)		-2.91
95% CI		(-19.13, 13.31)
p-value [1]		0.843

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.1
Summary and Analysis of Proportion of Subjects with Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	7 (12.1%)	2 (3.1%)
Odds Ratio		0.24
95% CI		(0.05, 1.18)
Relative Risk		0.26
95% CI		(0.06, 1.20)
Risk Difference (%)		-8.94
95% CI		(-18.35, 0.46)
p-value [1]		0.084

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.1
Summary and Analysis of Proportion of Subjects with Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	4 (6.9%)	1 (1.6%)
Odds Ratio		0.21
95% CI		(0.00, 2.28)
Relative Risk		0.23
95% CI		(0.03, 1.97)
Risk Difference (%)		-5.33
95% CI		(-12.53, 1.86)
p-value [1]		0.190

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.1
Summary and Analysis of Proportion of Subjects with Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	62	76
Any event	17 (27.4%)	18 (23.7%)
Odds Ratio		0.82
95% CI		(0.38, 1.77)
Relative Risk		0.86
95% CI		(0.49, 1.53)
Risk Difference (%)		-3.74
95% CI		(-18.39, 10.92)
p-value [1]		0.696

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.1
Summary and Analysis of Proportion of Subjects with Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	6 (9.7%)	1 (1.3%)
Odds Ratio		0.12
95% CI		(0.00, 1.08)
Relative Risk		0.14
95% CI		(0.02, 1.10)
Risk Difference (%)		-8.36
95% CI		(-16.15, -0.57)
p-value [1]		0.046

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.1
Summary and Analysis of Proportion of Subjects with Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (3.2%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.23
95% CI		(-7.62, 1.17)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.1
Summary and Analysis of Proportion of Subjects with Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	185	167
Any event	57 (30.8%)	37 (22.2%)
Odds Ratio		0.64
95% CI		(0.40, 1.03)
Relative Risk		0.72
95% CI		(0.50, 1.03)
Risk Difference (%)		-8.66
95% CI		(-17.82, 0.51)
p-value [1]		0.072

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 213.1
Summary and Analysis of Proportion of Subjects with Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	23 (12.4%)	8 (4.8%)
Odds Ratio		0.35
95% CI		(0.15, 0.82)
Relative Risk		0.39
95% CI		(0.18, 0.84)
Risk Difference (%)		-7.64
95% CI		(-13.40, -1.89)
p-value [1]		0.014

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.1
Summary and Analysis of Proportion of Subjects with Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	15 (8.1%)	2 (1.2%)
Odds Ratio		0.14
95% CI		(0.02, 0.61)
Relative Risk		0.15
95% CI		(0.03, 0.64)
Risk Difference (%)		-6.91
95% CI		(-11.18, -2.65)
p-value [1]		0.003

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Table 213.2
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	97	101
Any event	0	2 (2.0%)
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		1.98 (-0.74, 4.70)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 213.2
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	0	2 (2.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		1.98
95% CI		(-0.74, 4.70)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 213.2
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	0	1 (1.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		0.99
95% CI		(-0.94, 2.92)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.2
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	87	76
Any event	3 (3.4%)	2 (2.6%)
Odds Ratio		0.76
95% CI		(0.12, 4.65)
Relative Risk		0.76
95% CI		(0.13, 4.45)
Risk Difference (%)		-0.82
95% CI		(-6.08, 4.44)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.2
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	2 (2.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-2.30
95% CI		(-5.45, 0.85)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.2
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.2
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	5 (8.6%)	1 (1.6%)
Odds Ratio		0.17
95% CI		(0.00, 1.59)
Relative Risk		0.18
95% CI		(0.02, 1.51)
Risk Difference (%)		-7.06
95% CI		(-14.89, 0.78)
p-value [1]		0.102

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.2
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	5 (8.6%)	1 (1.6%)
Odds Ratio		0.17
95% CI		(0.00, 1.59)
Relative Risk		0.18
95% CI		(0.02, 1.51)
Risk Difference (%)		-7.06
95% CI		(-14.89, 0.78)
p-value [1]		0.102

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Table 213.2
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	4 (6.9%)	1 (1.6%)
Odds Ratio		0.21
95% CI		(0.00, 2.28)
Relative Risk		0.23
95% CI		(0.03, 1.97)
Risk Difference (%)		-5.33
95% CI		(-12.53, 1.86)
p-value [1]		0.190

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.2
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	62	76
Any event	3 (4.8%)	1 (1.3%)
Odds Ratio		0.26
95% CI		(0.00, 3.39)
Relative Risk		0.27
95% CI		(0.03, 2.55)
Risk Difference (%)		-3.52
95% CI		(-9.45, 2.40)
p-value [1]		0.327

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.2
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	2 (3.2%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.23
95% CI		(-7.62, 1.17)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 213.2
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (3.2%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.23
95% CI		(-7.62, 1.17)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 213.2
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	185	167
Any event	23 (12.4%)	4 (2.4%)
Odds Ratio		0.17
95% CI		(0.06, 0.51)
Relative Risk		0.19
95% CI		(0.07, 0.55)
Risk Difference (%)		-10.04
95% CI		(-15.33, -4.75)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 213.2
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	15 (8.1%)	2 (1.2%)
Odds Ratio		0.14
95% CI		(0.02, 0.61)
Relative Risk		0.15
95% CI		(0.03, 0.64)
Risk Difference (%)		-6.91
95% CI		(-11.18, -2.65)
p-value [1]		0.003

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.2
Summary and Analysis of Proportion of Subjects with Serious Adverse Events by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	13 (7.0%)	1 (0.6%)
Odds Ratio		0.08
95% CI		(0.00, 0.54)
Relative Risk		0.09
95% CI		(0.01, 0.64)
Risk Difference (%)		-6.43
95% CI		(-10.29, -2.56)
p-value [1]		0.002

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.3
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	97	101
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.3
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	87	76
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.3
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	1 (1.7%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.3
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	62	76
Any event	1 (1.6%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.3
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	185	167
Any event	3 (1.6%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.4
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	97	101
Any event	0	2 (2.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).
PPD

Table 213.4
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	87	76
Any event	1 (1.1%)	1 (1.3%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Table 213.4
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	0	1 (1.6%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Population: Safety

Table 213.4
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	62	76
Any event	3 (4.8%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Population: Safety

Table 213.4
Summary and Analysis of Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	185	167
Any event	2 (1.1%)	2 (1.2%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).
PPD

Population: Safety

Table 213.5
Summary and Analysis of Proportion of Subjects with Cardiac Events of Special Interest by Week 24 Baseline Viral Load

No data to report

Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.
PPD

Protocol: 214367
Population: Safety

Table 213.6
Summary and Analysis of Proportion of Subjects with Serious Infusion-Related Reactions including Hypersensitivity by Week 24 Baseline Viral Load

No data to report

Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Population: Safety

Table 213.7
Summary and Analysis of Proportion of Subjects with Serious Cardiac Events of Special Interest by Week 24 Baseline Viral Load

No data to report

Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.
PPD

Protocol: 214367
Population: Safety

Table 213.8
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	97	101
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.8
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	87	76
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.8
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	1 (1.7%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.8
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	62	76
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 213.8
Summary and Analysis of Proportion of Subjects with Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	185	167
Any event	4 (2.2%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Protocol: 214367
Population: Safety

Table 213.9
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	97	101
Any event	0	2 (2.0%)
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		1.98 (-0.74, 4.70)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Table 213.9
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	0	2 (2.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		1.98
95% CI		(-0.74, 4.70)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Table 213.9
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	0	1 (1.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		0.99
95% CI		(-0.94, 2.92)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.9
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	87	76
Any event	3 (3.4%)	2 (2.6%)
Odds Ratio		0.76
95% CI		(0.12, 4.65)
Relative Risk		0.76
95% CI		(0.13, 4.45)
Risk Difference (%)		-0.82
95% CI		(-6.08, 4.44)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.9
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	2 (2.3%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-2.30
95% CI		(-5.45, 0.85)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.9
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.9
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	4 (6.9%)	1 (1.6%)
Odds Ratio		0.21
95% CI		(0.00, 2.28)
Relative Risk		0.23
95% CI		(0.03, 1.97)
Risk Difference (%)		-5.33
95% CI		(-12.53, 1.86)
p-value [1]		0.190

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Table 213.9
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	4 (6.9%)	1 (1.6%)
Odds Ratio		0.21
95% CI		(0.00, 2.28)
Relative Risk		0.23
95% CI		(0.03, 1.97)
Risk Difference (%)		-5.33
95% CI		(-12.53, 1.86)
p-value [1]		0.190

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.9
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	3 (5.2%)	1 (1.6%)
Odds Ratio		0.29
95% CI		(0.01, 3.78)
Relative Risk		0.30
95% CI		(0.03, 2.82)
Risk Difference (%)		-3.61
95% CI		(-10.07, 2.85)
p-value [1]		0.346

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.9
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	62	76
Any event	3 (4.8%)	1 (1.3%)
Odds Ratio		0.26
95% CI		(0.00, 3.39)
Relative Risk		0.27
95% CI		(0.03, 2.55)
Risk Difference (%)		-3.52
95% CI		(-9.45, 2.40)
p-value [1]		0.327

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 213.9
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	2 (3.2%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.23
95% CI		(-7.62, 1.17)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Population: Safety

Table 213.9
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (3.2%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.23
95% CI		(-7.62, 1.17)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.9
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	185	167
Any event	20 (10.8%)	4 (2.4%)
Odds Ratio		0.20
95% CI		(0.07, 0.61)
Relative Risk		0.22
95% CI		(0.08, 0.63)
Risk Difference (%)		-8.42
95% CI		(-13.46, -3.38)
p-value [1]		0.003

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.9
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	13 (7.0%)	2 (1.2%)
Odds Ratio		0.16
95% CI		(0.02, 0.73)
Relative Risk		0.17
95% CI		(0.04, 0.74)
Risk Difference (%)		-5.83
95% CI		(-9.87, -1.79)
p-value [1]		0.008

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.9
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	12 (6.5%)	1 (0.6%)
Odds Ratio		0.09
95% CI		(0.00, 0.60)
Relative Risk		0.09
95% CI		(0.01, 0.70)
Risk Difference (%)		-5.89
95% CI		(-9.62, -2.15)
p-value [1]		0.004

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Table 213.10
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Adverse Events

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.187
Infections and infestations Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.365
Infections and infestations COVID-19 pneumonia	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.999

[1] Interaction p-values obtained from separate logistic regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Population: Safety

Table 213.11
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Adverse Events

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.737
Infections and infestations Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	>0.999
Infections and infestations COVID-19 pneumonia	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.981

[1] Interaction p-values obtained from separate logistic regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Table 213.12
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Adverse Events Leading to Withdrawal from Study

No data to report

PPD

Population: Safety

Table 213.13
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Infusion-Related Reactions including Hypersensitivity

Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	>0.999

[1] Interaction p-values obtained from separate logistic regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.
Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).
PPD

Population: Safety

Table 213.14
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Cardiac Events of Special Interest

No data to report

Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.
PPD

Protocol: 214367
Population: Safety

Table 213.15
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Infusion-Related Reactions including Hypersensitivity

No data to report

Note: Infusion-related reactions (including hypersensitivity) are defined using a selection of preferred terms and only includes events that started within 24 hours of study treatment (or AEs that started on day 1 or day 2 if AE onset time is missing).

PPD

Protocol: 214367
Population: Safety

Table 213.16
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Cardiac Events of Special Interest

No data to report

Note: Cardiac events are defined using a selection of sub-SMQs and selected preferred terms.
PPD

Table 213.17
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Fatal Serious Adverse Events

No data to report

PPD

Population: Safety

Table 213.18
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Non-Fatal Serious Adverse Events

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.819
Infections and infestations Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	>0.999
Infections and infestations COVID-19 pneumonia	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.963

[1] Interaction p-values obtained from separate logistic regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Population: Safety

Table 213.19
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	97	101
Any event	4 (4.1%)	4 (4.0%)
Odds Ratio		0.96
95% CI		(0.23, 3.95)
Relative Risk		0.96
95% CI		(0.25, 3.73)
Risk Difference (%)		-0.16
95% CI		(-5.65, 5.33)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.

PPD

Table 213.19
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	0	2 (2.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		1.98
95% CI		(-0.74, 4.70)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.19
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	0	1 (1.0%)
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		0.99
95% CI		(-0.94, 2.92)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.19
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	87	76
Any event	3 (3.4%)	4 (5.3%)
Odds Ratio		1.56
95% CI		(0.34, 7.18)
Relative Risk		1.53
95% CI		(0.35, 6.61)
Risk Difference (%)		1.81
95% CI		(-4.50, 8.13)
p-value [1]		0.707

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.19
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.19
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	0	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		
95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.19
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	6 (10.3%)	1 (1.6%)
Odds Ratio		0.14
95% CI		(0.00, 1.21)
Relative Risk		0.15
95% CI		(0.02, 1.22)
Risk Difference (%)		-8.78
95% CI		(-17.19, -0.38)
p-value [1]		0.053

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.19
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	5 (8.6%)	1 (1.6%)
Odds Ratio		0.17
95% CI		(0.00, 1.59)
Relative Risk		0.18
95% CI		(0.02, 1.51)
Risk Difference (%)		-7.06
95% CI		(-14.89, 0.78)
p-value [1]		0.102

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.19
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	4 (6.9%)	1 (1.6%)
Odds Ratio		0.21
95% CI		(0.00, 2.28)
Relative Risk		0.23
95% CI		(0.03, 1.97)
Risk Difference (%)		-5.33
95% CI		(-12.53, 1.86)
p-value [1]		0.190

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.19
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	62	76
Any event	4 (6.5%)	6 (7.9%)
Odds Ratio		1.24
95% CI		(0.33, 4.62)
Relative Risk		1.22
95% CI		(0.36, 4.14)
Risk Difference (%)		1.44
95% CI		(-7.17, 10.05)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.19
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	2 (3.2%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.23
95% CI		(-7.62, 1.17)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.19
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	2 (3.2%)	0
Odds Ratio		
95% CI		
Relative Risk		
95% CI		
Risk Difference (%)		-3.23
95% CI		(-7.62, 1.17)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.19
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	185	167
Any event	26 (14.1%)	6 (3.6%)
Odds Ratio		0.23
95% CI		(0.09, 0.57)
Relative Risk		0.26
95% CI		(0.11, 0.61)
Risk Difference (%)		-10.46
95% CI		(-16.21, -4.71)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.19
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	17 (9.2%)	2 (1.2%)
Odds Ratio		0.12
95% CI		(0.01, 0.52)
Relative Risk		0.13
95% CI		(0.03, 0.56)
Risk Difference (%)		-7.99
95% CI		(-12.47, -3.51)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Population: Safety

Table 213.19
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3
by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
COVID-19 pneumonia	14 (7.6%)	1 (0.6%)
Odds Ratio		0.07
95% CI		(0.00, 0.50)
Relative Risk		0.08
95% CI		(0.01, 0.60)
Risk Difference (%)		-6.97
95% CI		(-10.96, -2.98)
p-value [1]		<0.001

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
PPD

Protocol: 214367
Population: Safety

Table 213.20
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.062
Infections and infestations Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	>0.999
Infections and infestations COVID-19 pneumonia	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.975

[1] Interaction p-values obtained from separate logistic regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Table 213.21
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	97	101
Any event	22 (22.7%)	24 (23.8%)
Odds Ratio		1.06
95% CI		(0.55, 2.06)
Relative Risk		1.05
95% CI		(0.63, 1.74)
Risk Difference (%)		1.08
95% CI		(-10.68, 12.84)
p-value [1]		0.869

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 213.21
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	4 (4.1%)	4 (4.0%)
Odds Ratio		0.96
95% CI		(0.23, 3.95)
Relative Risk		0.96
95% CI		(0.25, 3.73)
Risk Difference (%)		-0.16
95% CI		(-5.65, 5.33)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 213.21
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	87	76
Any event	18 (20.7%)	22 (28.9%)
Odds Ratio		1.56
95% CI		(0.76, 3.20)
Relative Risk		1.40
95% CI		(0.81, 2.40)
Risk Difference (%)		8.26
95% CI		(-5.02, 21.54)
p-value [1]		0.275

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 213.21
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	7 (8.0%)	4 (5.3%)
Odds Ratio		0.63
95% CI		(0.18, 2.26)
Relative Risk		0.65
95% CI		(0.20, 2.15)
Risk Difference (%)		-2.78
95% CI		(-10.39, 4.82)
p-value [1]		0.546

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 213.21
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	14 (24.1%)	16 (25.0%)
Odds Ratio		1.05
95% CI		(0.46, 2.39)
Relative Risk		1.04
95% CI		(0.56, 1.93)
Risk Difference (%)		0.86
95% CI		(-14.43, 16.15)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.
PPD

Population: Safety

Table 213.21
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	3 (5.2%)	1 (1.6%)
Odds Ratio		0.29
95% CI		(0.01, 3.78)
Relative Risk		0.30
95% CI		(0.03, 2.82)
Risk Difference (%)		-3.61
95% CI		(-10.07, 2.85)
p-value [1]		0.346

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 213.21
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	62	76
Any event	15 (24.2%)	18 (23.7%)
Odds Ratio		0.97
95% CI		(0.44, 2.13)
Relative Risk		0.98
95% CI		(0.54, 1.78)
Risk Difference (%)		-0.51
95% CI		(-14.83, 13.81)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.
PPD

Population: Safety

Table 213.21
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	5 (8.1%)	1 (1.3%)
Odds Ratio		0.15
95% CI		(0.00, 1.43)
Relative Risk		0.16
95% CI		(0.02, 1.36)
Risk Difference (%)		-6.75
95% CI		(-13.99, 0.50)
p-value [1]		0.090

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 213.21
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	185	167
Any event	47 (25.4%)	37 (22.2%)
Odds Ratio		0.84
95% CI		(0.51, 1.37)
Relative Risk		0.87
95% CI		(0.60, 1.27)
Risk Difference (%)		-3.25
95% CI		(-12.14, 5.64)
p-value [1]		0.532

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 213.21
Summary and Analysis of Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Infections and infestations		
Any event	14 (7.6%)	6 (3.6%)
Odds Ratio		0.46
95% CI		(0.17, 1.21)
Relative Risk		0.47
95% CI		(0.19, 1.21)
Risk Difference (%)		-3.97
95% CI		(-8.72, 0.77)
p-value [1]		0.166

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 213.22
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	97	101
Any event	4 (4.1%)	4 (4.0%)
Odds Ratio		0.96
95% CI		(0.23, 3.95)
Relative Risk		0.96
95% CI		(0.25, 3.73)
Risk Difference (%)		-0.16
95% CI		(-5.65, 5.33)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 213.22
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	87	76
Any event	3 (3.4%)	4 (5.3%)
Odds Ratio		1.56
95% CI		(0.34, 7.18)
Relative Risk		1.53
95% CI		(0.35, 6.61)
Risk Difference (%)		1.81
95% CI		(-4.50, 8.13)
p-value [1]		0.707

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.
PPD

Population: Safety

Table 213.22
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	2 (3.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-3.45 (-8.14, 1.25)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.
PPD

Population: Safety

Table 213.22
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	62	76
Any event	2 (3.2%)	6 (7.9%)
Odds Ratio		2.57
95% CI		(0.50, 13.22)
Relative Risk		2.45
95% CI		(0.51, 11.70)
Risk Difference (%)		4.67
95% CI		(-2.82, 12.16)
p-value [1]		0.296

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 213.22
Summary and Analysis of Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	185	167
Any event	16 (8.6%)	6 (3.6%)
Odds Ratio		0.39
95% CI		(0.15, 1.03)
Relative Risk		0.42
95% CI		(0.17, 1.04)
Risk Difference (%)		-5.06
95% CI		(-9.99, -0.12)
p-value [1]		0.076

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.
PPD

Population: Safety

Table 213.23
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	97	101
Any event	0	2 (2.0%)
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		1.98 (-0.74, 4.70)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.
PPD

Population: Safety

Table 213.23
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	87	76
Any event	3 (3.4%)	2 (2.6%)
Odds Ratio		0.76
95% CI		(0.12, 4.65)
Relative Risk		0.76
95% CI		(0.13, 4.45)
Risk Difference (%)		-0.82
95% CI		(-6.08, 4.44)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 213.23
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	2 (3.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-3.45 (-8.14, 1.25)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 213.23
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	62	76
Any event	1 (1.6%)	1 (1.3%)
Odds Ratio		0.81
95% CI		(0.01, 64.88)
Relative Risk		0.82
95% CI		(0.05, 12.78)
Risk Difference (%)		-0.30
95% CI		(-4.35, 3.75)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.
PPD

Population: Safety

Table 213.23
Summary and Analysis of Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	185	167
Any event	12 (6.5%)	3 (1.8%)
Odds Ratio		0.26
95% CI		(0.05, 1.00)
Relative Risk		0.28
95% CI		(0.08, 0.96)
Risk Difference (%)		-4.69
95% CI		(-8.77, -0.61)
p-value [1]		0.035

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 213.24
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	97	101
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.

PPD

Population: Safety

Table 213.24
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	87	76
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.
PPD

Population: Safety

Table 213.24
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	0	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.
PPD

Population: Safety

Table 213.24
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	62	76
Any event	1 (1.6%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.
PPD

Population: Safety

Table 213.24
Summary and Analysis of Proportion of Subjects with Adverse Events Leading to Withdrawal from Study
Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	185	167
Any event	2 (1.1%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.
PPD

Population: Safety

Table 213.25
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	97	101
Any event	0	2 (2.0%)
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		1.98 (-0.74, 4.70)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.
PPD

Population: Safety

Table 213.25
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	87	76
Any event	3 (3.4%)	2 (2.6%)
Odds Ratio		0.76
95% CI		(0.12, 4.65)
Relative Risk		0.76
95% CI		(0.13, 4.45)
Risk Difference (%)		-0.82
95% CI		(-6.08, 4.44)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.
PPD

Population: Safety

Table 213.25
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	58	64
Any event	2 (3.4%)	0
Odds Ratio 95% CI		
Relative Risk 95% CI		
Risk Difference (%) 95% CI		-3.45 (-8.14, 1.25)
p-value [1]		

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.
PPD

Population: Safety

Table 213.25
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	62	76
Any event	1 (1.6%)	1 (1.3%)
Odds Ratio		0.81
95% CI		(0.01, 64.88)
Relative Risk		0.82
95% CI		(0.05, 12.78)
Risk Difference (%)		-0.30
95% CI		(-4.35, 3.75)
p-value [1]		>0.999

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.
PPD

Population: Safety

Table 213.25
Summary and Analysis of Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

System Organ Class Preferred Term	Placebo (N=526)	Sotrovimab (500mg IV) (N=523)
Number of subjects in subgroup	185	167
Any event	10 (5.4%)	3 (1.8%)
Odds Ratio		0.32
95% CI		(0.06, 1.28)
Relative Risk		0.33
95% CI		(0.09, 1.19)
Risk Difference (%)		-3.61
95% CI		(-7.44, 0.22)
p-value [1]		0.092

Note: For proportions below 2% in any treatment group included in the treatment comparison the associated 95% CI for the odds ratio is calculated using the Clopper-Pearson method, otherwise the 95% CI is calculated using the Wald method.
[1] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: The relative risk, odds ratio and absolute risk difference are calculated based on the raw numbers/frequencies.
Note: Excludes AEs related to COVID-19 (selected preferred terms) that started >24 hours post-dose up to and including 10 days post-dose.
PPD

Population: Safety

Table 213.26
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Adverse Events Excluding Events Related to COVID-19

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.734
Infections and infestations Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.672

[1] Interaction p-values obtained from separate logistic regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Population: Safety

Table 213.27
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Severe Adverse Events with DAIDS Grade >=3 Excluding Events Related to COVID-19

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.306

[1] Interaction p-values obtained from separate logistic regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Population: Safety

Table 213.28
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Serious Adverse Events Excluding Events Related to COVID-19

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.891

[1] Interaction p-values obtained from separate logistic regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Table 213.29
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Adverse Events Leading to Withdrawal from Study Excluding Events Related to COVID-19

No data to report

PPD

Population: Safety

Table 213.30
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects with Non-Fatal Serious Adverse Events Excluding Events Related to COVID-19

System Organ Class Preferred Term	Interaction of Treatment with:	P-value [1]
Any event	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.946

[1] Interaction p-values obtained from separate logistic regression models with covariates of treatment group, subgroup plus subgroup by treatment group interaction term.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 214.1
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

		Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup	97	101
Day 7	Number of subjects with event	7 (7%)	18 (18%)
	Number of subjects censored	0	0
	Number of subjects without event	90 (93%)	83 (82%)
	Probability of having event [1]	7.2%	17.8%
	95% C.I.	(3.5%, 14.5%)	(11.6%, 26.8%)
Day 14	Number of subjects with event	23 (24%)	33 (33%)
	Number of subjects censored	0	0
	Number of subjects without event	74 (76%)	68 (67%)
	Probability of having event [1]	23.7%	32.7%
	95% C.I.	(16.4%, 33.5%)	(24.5%, 42.7%)
Day 21	Number of subjects with event	37 (38%)	42 (42%)
	Number of subjects censored	60 (62%)	59 (58%)
	Number of subjects without event	0	0
	Probability of having event [1]	38.1%	41.6%
	95% C.I.	(29.3%, 48.6%)	(32.7%, 51.8%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction term. Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.
PPD

Population: Intent-to-Treat

Table 214.1
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
First quartile (95% C.I.) time to onset (days)	15 (10,18)	12 (6,15)
Median (95% C.I.) time to onset (days)	NE (NE,NE)	NE (18,NE)
Third quartile (95% C.I.) time to onset (days)	NE (NE,NE)	NE (NE,NE)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.84
95% C.I.		(0.54, 1.31)
p-value		0.437

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction term. Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.
PPD

Population: Intent-to-Treat

Table 214.1
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

		Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup	87	76
Day 7	Number of subjects with event	7 (8%)	14 (18%)
	Number of subjects censored	0	0
	Number of subjects without event	80 (92%)	62 (82%)
	Probability of having event [1]	8.0%	18.4%
	95% C.I.	(3.9%, 16.1%)	(11.3%, 29.1%)
Day 14	Number of subjects with event	20 (23%)	35 (46%)
	Number of subjects censored	0	0
	Number of subjects without event	67 (77%)	41 (54%)
	Probability of having event [1]	23.0%	46.1%
	95% C.I.	(15.5%, 33.3%)	(35.6%, 57.9%)
Day 21	Number of subjects with event	41 (47%)	41 (54%)
	Number of subjects censored	46 (53%)	35 (46%)
	Number of subjects without event	0	0
	Probability of having event [1]	47.1%	53.9%
	95% C.I.	(37.3%, 58.1%)	(43.3%, 65.4%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction term. Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.
PPD

Population: Intent-to-Treat

Table 214.1
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
First quartile (95% C.I.) time to onset (days)	15 (11,17)	8 (6,10)
Median (95% C.I.) time to onset (days)	NE (17,NE)	19 (12,NE)
Third quartile (95% C.I.) time to onset (days)	NE (NE,NE)	NE (NE,NE)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.71
95% C.I.		(0.46, 1.09)
p-value		0.121

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction term. Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.
PPD

Protocol: 214367
Population: Intent-to-Treat

Table 214.1
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

		Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup	58	64
Day 7	Number of subjects with event	6 (10%)	11 (17%)
	Number of subjects censored	0	1 (2%)
	Number of subjects without event	52 (90%)	52 (81%)
	Probability of having event [1]	10.3%	17.3%
	95% C.I.	(4.8%, 21.6%)	(10.0%, 29.1%)
Day 14	Number of subjects with event	20 (34%)	20 (31%)
	Number of subjects censored	0	1 (2%)
	Number of subjects without event	38 (66%)	43 (67%)
	Probability of having event [1]	34.5%	31.7%
	95% C.I.	(23.8%, 48.2%)	(21.7%, 44.7%)
Day 21	Number of subjects with event	31 (53%)	29 (45%)
	Number of subjects censored	27 (47%)	35 (55%)
	Number of subjects without event	0	0
	Probability of having event [1]	53.4%	46.2%
	95% C.I.	(41.3%, 66.6%)	(34.8%, 59.3%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction term. Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.
PPD

Population: Intent-to-Treat

Table 214.1
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
First quartile (95% C.I.) time to onset (days)	13 (10,15)	11 (7,16)
Median (95% C.I.) time to onset (days)	19 (15,NE)	NE (17,NE)
Third quartile (95% C.I.) time to onset (days)	NE (NE,NE)	NE (NE,NE)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		1.16
95% C.I.		(0.70, 1.92)
p-value		0.569

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction term. Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.
PPD

Protocol: 214367
Population: Intent-to-Treat

Table 214.1
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

		Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup	62	77
Day 7	Number of subjects with event	4 (6%)	9 (12%)
	Number of subjects censored	0	1 (1%)
	Number of subjects without event	58 (94%)	67 (87%)
	Probability of having event [1]	6.5%	11.8%
	95% C.I.	(2.5%, 16.3%)	(6.3%, 21.5%)
Day 14	Number of subjects with event	14 (23%)	21 (27%)
	Number of subjects censored	1 (2%)	1 (1%)
	Number of subjects without event	47 (76%)	55 (71%)
	Probability of having event [1]	22.8%	27.6%
	95% C.I.	(14.2%, 35.4%)	(19.0%, 39.2%)
Day 21	Number of subjects with event	20 (32%)	29 (38%)
	Number of subjects censored	42 (68%)	48 (62%)
	Number of subjects without event	0	0
	Probability of having event [1]	32.6%	38.2%
	95% C.I.	(22.4%, 45.9%)	(28.3%, 50.0%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction term. Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.
PPD

Population: Intent-to-Treat

Table 214.1
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
First quartile (95% C.I.) time to onset (days)	15 (12,NE)	13 (11,18)
Median (95% C.I.) time to onset (days)	NE (NE,NE)	NE (20,NE)
Third quartile (95% C.I.) time to onset (days)	NE (NE,NE)	NE (NE,NE)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.81
95% C.I.		(0.46, 1.43)
p-value		0.469

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction term. Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.
PPD

Protocol: 214367
Population: Intent-to-Treat

Table 214.1
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

		Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup	187	166
Day 7	Number of subjects with event	8 (4%)	14 (8%)
	Number of subjects censored	3 (2%)	0
	Number of subjects without event	176 (94%)	152 (92%)
	Probability of having event [1]	4.3%	8.4%
	95% C.I.	(2.2%, 8.5%)	(5.1%, 13.8%)
Day 14	Number of subjects with event	27 (14%)	38 (23%)
	Number of subjects censored	3 (2%)	0
	Number of subjects without event	157 (84%)	128 (77%)
	Probability of having event [1]	14.7%	22.9%
	95% C.I.	(10.3%, 20.6%)	(17.2%, 30.1%)
Day 21	Number of subjects with event	49 (26%)	53 (32%)
	Number of subjects censored	138 (74%)	113 (68%)
	Number of subjects without event	0	0
	Probability of having event [1]	26.8%	31.9%
	95% C.I.	(21.0%, 33.8%)	(25.4%, 39.6%)

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction term. Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.
PPD

Population: Intent-to-Treat

Table 214.1
Summary and Analysis of Time to Sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
First quartile (95% C.I.) time to onset (days)	20 (18,NE)	15 (12,21)
Median (95% C.I.) time to onset (days)	NE (NE,NE)	NE (NE,NE)
Third quartile (95% C.I.) time to onset (days)	NE (NE,NE)	NE (NE,NE)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.78
95% C.I.		(0.53, 1.14)
p-value		0.202

[1] Probability of having event is taken at the end of day.
Note: Event=sustained (>=48 hours) symptom alleviation. Subjects without the event are censored at the earliest of (randomization+20, death date, study withdrawal date). Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with covariates of treatment, week 24 baseline viral load category and treatment by week 24 baseline viral load category interaction term. Note: Inverse hazard ratio <1 corresponds to a benefit of sotrovimab over placebo.
PPD

Population: Intent-to-Treat

Table 214.2
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 21

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	37 (38%)	42 (42%)
Not sustained symptom alleviation	60 (62%)	59 (58%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [1]		0.88
95% C.I.		(0.50, 1.56)
p-value		0.669
Inverse Relative Risk [2]		0.93
95% C.I.		(0.66, 1.31)
p-value		0.669
Risk Difference (%) [3]		-3.44
95% C.I.		(-17.07, 10.19)
p-value		0.665

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >=70 years old), week 24 baseline viral load category, gender(male, female) and week 24 baseline viral load category by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.

PPD

Population: Intent-to-Treat

Table 214.2
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 21

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	41 (47%)	41 (54%)
Not sustained symptom alleviation	46 (53%)	35 (46%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [1]		0.76
95% C.I.		(0.41, 1.41)
p-value		0.385
Inverse Relative Risk [2]		0.87
95% C.I.		(0.65, 1.19)
p-value		0.388
Risk Difference (%) [3]		-6.82
95% C.I.		(-22.17, 8.53)
p-value		0.434

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >=70 years old), week 24 baseline viral load category, gender(male, female) and week 24 baseline viral load category by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.

PPD

Population: Intent-to-Treat

Table 214.2
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 21

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	31 (53%)	29 (45%)
Not sustained symptom alleviation	27 (47%)	35 (55%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [1]		1.52
95% C.I.		(0.74, 3.13)
p-value		0.257
Inverse Relative Risk [2]		1.24
95% C.I.		(0.87, 1.77)
p-value		0.241
Risk Difference (%) [3]		8.14
95% C.I.		(-9.57, 25.84)
p-value		0.469

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >=70 years old), week 24 baseline viral load category, gender(male, female) and week 24 baseline viral load category by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.

PPD

Population: Intent-to-Treat

Table 214.2
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 21

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	62	77
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	20 (32%)	29 (38%)
Not sustained symptom alleviation	42 (68%)	48 (62%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [1]		0.76
95% C.I.		(0.37, 1.54)
p-value		0.444
Inverse Relative Risk [2]		0.84
95% C.I.		(0.53, 1.32)
p-value		0.445
Risk Difference (%) [3]		-5.40
95% C.I.		(-21.30, 10.49)
p-value		0.593

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >=70 years old), week 24 baseline viral load category, gender(male, female) and week 24 baseline viral load category by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.

PPD

Population: Intent-to-Treat

Table 214.2
Summary and Analysis of Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 21

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
Symptom Alleviation Status, n (%)		
Sustained (>=48 hr) symptom alleviation	49 (26%)	53 (32%)
Not sustained symptom alleviation	138 (74%)	113 (68%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [1]		0.73
95% C.I.		(0.46, 1.17)
p-value		0.195
Inverse Relative Risk [2]		0.81
95% C.I.		(0.58, 1.12)
p-value		0.203
Risk Difference (%) [3]		-5.72
95% C.I.		(-15.21, 3.76)
p-value		0.243

Note: Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Days where symptom alleviation cannot be assessed due to a missing/incomplete questionnaire are imputed as no symptom alleviation.
Note: Analysis was performed adjusting for region (North America, Europe, South America), treatment, duration of symptoms (<=3, >=4 days), age (<=70, >=70 years old), week 24 baseline viral load category, gender(male, female) and week 24 baseline viral load category by treatment interaction, using [1] logistic regression, [2] Poisson model.
[3] P-value is calculated using a 2-sided Fisher’s Exact test.

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Protocol: 214367
Population: Intent-to-Treat

Table 214.3
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 21

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
FLU-PRO Plus Responder Status, n (%)		
Responder	42 (43%)	59 (58%)
Non-responder	27 (28%)	19 (19%)
Missing [1]	28 (29%)	23 (23%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.54
95% C.I.		(0.31, 0.96)
p-value		0.035
Inverse Relative Risk [3]		0.74
95% C.I.		(0.56, 0.98)
p-value		0.037
Risk Difference (%) [4]		-15.12
95% C.I.		(-28.89, -1.35)
p-value		0.047

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
PPD

Population: Intent-to-Treat

Table 214.3
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 21

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
FLU-PRO Plus Responder Status, n (%)		
Responder	49 (56%)	40 (53%)
Non-responder	17 (20%)	18 (24%)
Missing [1]	21 (24%)	18 (24%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.16
95% C.I.		(0.63, 2.15)
p-value		0.637
Inverse Relative Risk [3]		1.07
95% C.I.		(0.81, 1.42)
p-value		0.639
Risk Difference (%) [4]		3.69
95% C.I.		(-11.63, 19.01)
p-value		0.753

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.

PPD

Population: Intent-to-Treat

Table 214.3
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 21

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
FLU-PRO Plus Responder Status, n (%)		
Responder	30 (52%)	30 (47%)
Non-responder	12 (21%)	16 (25%)
Missing [1]	16 (28%)	18 (28%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.21
95% C.I.		(0.60, 2.47)
p-value		0.593
Inverse Relative Risk [3]		1.10
95% C.I.		(0.77, 1.58)
p-value		0.593
Risk Difference (%) [4]		4.85
95% C.I.		(-12.89, 22.59)
p-value		0.718

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.

PPD

Population: Intent-to-Treat

Table 214.3
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 21

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	62	77
FLU-PRO Plus Responder Status, n (%)		
Responder	29 (47%)	39 (51%)
Non-responder	13 (21%)	18 (23%)
Missing [1]	20 (32%)	20 (26%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.86
95% C.I.		(0.44, 1.67)
p-value		0.650
Inverse Relative Risk [3]		0.92
95% C.I.		(0.65, 1.30)
p-value		0.652
Risk Difference (%) [4]		-3.88
95% C.I.		(-20.58, 12.83)
p-value		0.734

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.

PPD

Population: Intent-to-Treat

Table 214.3
Summary and Analysis of Proportion of FLU-PRO Plus Total Score Responders at Day 21 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 21

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
FLU-PRO Plus Responder Status, n (%)		
Responder	79 (42%)	80 (48%)
Non-responder	38 (20%)	48 (29%)
Missing [1]	70 (37%)	38 (23%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.79
95% C.I.		(0.52, 1.20)
p-value		0.263
Inverse Relative Risk [3]		0.88
95% C.I.		(0.70, 1.10)
p-value		0.263
Risk Difference (%) [4]		-5.95
95% C.I.		(-16.33, 4.44)
p-value		0.285

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.

PPD

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		97	101
Baseline	Work time missed due to health (%)	n	25	31
		Mean	72.40	69.62
		SD	35.071	40.487
		Median	86.49	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	15	20
		Mean	28.15	6.44
		SD	40.042	22.667
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in work time missed due to health (%)	n	5	13
		Mean	-40.07	-51.78
		SD	59.067	47.485
		Median	-36.49	-33.33
		Min.	-100.0	-100.0
		Max.	18.2	0.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Impairment while working due to health (%)	n	10	10
		Mean	49.00	33.00
		SD	38.715	24.967
		Median	50.00	20.00
		Min.	0.0	10.0
		Max.	90.0	80.0
Day 29	Impairment while working due to health (%)	n	10	15
		Mean	21.00	13.33
		SD	16.633	11.751
		Median	20.00	10.00
		Min.	0.0	0.0
		Max.	50.0	50.0
	Change from baseline in impairment while working due to health (%)	n	2	6
		Mean	0.00	-21.67
		SD	70.711	19.408
		Median	0.00	-15.00
		Min.	-50.0	-50.0
		Max.	50.0	0.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Overall work impairment due to health (%)	n	10	10
		Mean	67.57	43.04
		SD	38.694	31.392
		Median	83.05	40.33
		Min.	0.0	10.0
		Max.	98.6	90.0
Day 29	Overall work impairment due to health (%)	n	10	15
		Mean	27.71	14.90
		SD	22.256	13.372
		Median	30.00	10.00
		Min.	0.0	0.0
		Max.	60.0	50.0
	Change from baseline in overall work impairment due to health (%)	n	2	6
		Mean	11.57	-28.35
		SD	67.201	20.425
		Median	11.57	-31.71
		Min.	-35.9	-50.0
		Max.	59.1	0.0

Note: WPAI was scheduled for the Expansion phase only.
PPD

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Activity impairment due to health (%)	n	49	49
		Mean	59.59	52.86
		SD	28.501	34.521
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	33	38
		Mean	23.64	17.37
		SD	24.726	21.395
		Median	10.00	10.00
		Min.	0.0	0.0
		Max.	90.0	90.0
	Change from baseline in activity impairment due to health (%)	n	24	27
		Mean	-31.25	-30.74
		SD	43.968	37.920
		Median	-50.00	-20.00
		Min.	-80.0	-80.0
		Max.	60.0	70.0

Note: WPAI was scheduled for the Expansion phase only.
PPD

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		87	76
Baseline	Work time missed due to health (%)	n	23	27
		Mean	56.85	68.30
		SD	41.224	33.572
		Median	66.67	70.59
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	8	13
		Mean	41.29	4.29
		SD	47.586	10.538
		Median	21.43	0.00
		Min.	0.0	0.0
		Max.	100.0	30.8
	Change from baseline in work time missed due to health (%)	n	6	7
		Mean	-22.02	-81.68
		SD	69.028	27.806
		Median	-8.75	-100.00
		Min.	-100.0	-100.0
		Max.	80.0	-40.0

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Impairment while working due to health (%)	n	8	4
		Mean	45.00	57.50
		SD	33.381	17.078
		Median	50.00	55.00
		Min.	10.0	40.0
		Max.	90.0	80.0
Day 29	Impairment while working due to health (%)	n	6	8
		Mean	23.33	12.50
		SD	15.055	11.650
		Median	20.00	10.00
		Min.	10.0	0.0
		Max.	40.0	40.0
	Change from baseline in impairment while working due to health (%)	n	0	0
		Mean		
		SD		
		Median		
		Min.		
		Max.		

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Overall work impairment due to health (%)	n	8	4
		Mean	51.76	77.94
		SD	37.098	9.276
		Median	57.94	75.32
		Min.	10.0	70.0
		Max.	94.9	91.1
Day 29	Overall work impairment due to health (%)	n	6	8
		Mean	36.37	15.96
		SD	35.038	14.553
		Median	20.00	10.00
		Min.	10.0	0.0
		Max.	92.5	40.0
	Change from baseline in overall work impairment due to health (%)	n	0	0
		Mean		
		SD		
		Median		
		Min.		
		Max.		

Note: WPAI was scheduled for the Expansion phase only.
PPD

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Activity impairment due to health (%)	n	33	25
		Mean	58.79	58.80
		SD	29.870	28.769
		Median	70.00	60.00
		Min.	0.0	10.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	31	24
		Mean	28.71	18.33
		SD	26.801	18.805
		Median	10.00	10.00
		Min.	0.0	0.0
		Max.	90.0	80.0
	Change from baseline in activity impairment due to health (%)	n	20	9
		Mean	-28.50	-48.89
		SD	40.817	31.002
		Median	-20.00	-40.00
		Min.	-90.0	-90.0
		Max.	50.0	-10.0

Note: WPAI was scheduled for the Expansion phase only.
PPD

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		58	64
Baseline	Work time missed due to health (%)	n	18	29
		Mean	52.41	69.03
		SD	38.515	37.845
		Median	46.89	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	11	14
		Mean	2.60	3.76
		SD	8.615	8.255
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	28.6	25.0
	Change from baseline in work time missed due to health (%)	n	5	11
		Mean	-25.67	-57.90
		SD	17.409	36.207
		Median	-20.00	-55.56
		Min.	-46.2	-100.0
		Max.	-9.1	0.0

Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Impairment while working due to health (%)	n	6	6
		Mean	43.33	51.67
		SD	21.602	33.116
		Median	45.00	55.00
		Min.	10.0	10.0
		Max.	70.0	100.0
Day 29	Impairment while working due to health (%)	n	5	10
		Mean	32.00	34.00
		SD	13.038	34.705
		Median	30.00	25.00
		Min.	20.0	0.0
		Max.	50.0	100.0
	Change from baseline in impairment while working due to health (%)	n	1	3
		Mean	10.00	-53.33
		SD		41.633
		Median	10.00	-40.00
		Min.	10.0	-100.0
		Max.	10.0	-20.0

Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Overall work impairment due to health (%)	n	6	5
		Mean	62.15	64.22
		SD	23.123	34.934
		Median	63.79	75.00
		Min.	24.4	10.0
		Max.	86.7	100.0
Day 29	Overall work impairment due to health (%)	n	5	9
		Mean	32.00	34.89
		SD	13.038	36.880
		Median	30.00	20.00
		Min.	20.0	0.0
		Max.	50.0	100.0
	Change from baseline in overall work impairment due to health (%)	n	1	2
		Mean	-15.26	-70.06
		SD		42.343
		Median	-15.26	-70.06
		Min.	-15.3	-100.0
		Max.	-15.3	-40.1

Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Activity impairment due to health (%)	n	24	24
		Mean	62.08	59.17
		SD	32.966	32.560
		Median	65.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	22	22
		Mean	33.18	23.64
		SD	24.179	24.794
		Median	25.00	10.00
		Min.	10.0	0.0
		Max.	90.0	90.0
	Change from baseline in activity impairment due to health (%)	n	13	14
		Mean	-30.00	-35.71
		SD	26.771	37.563
		Median	-40.00	-30.00
		Min.	-70.0	-100.0
		Max.	10.0	10.0

Note: WPAI was scheduled for the Expansion phase only.
PPD

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		62	77
Baseline	Work time missed due to health (%)	n	24	33
		Mean	49.23	49.55
		SD	37.678	41.193
		Median	43.25	44.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	12	21
		Mean	3.61	5.23
		SD	8.808	14.318
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	30.4	54.5
	Change from baseline in work time missed due to health (%)	n	8	15
		Mean	-44.33	-44.47
		SD	43.640	50.707
		Median	-37.62	-50.00
		Min.	-100.0	-100.0
		Max.	0.0	49.5

Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Impairment while working due to health (%)	n	11	14
		Mean	51.82	47.14
		SD	36.005	31.727
		Median	60.00	55.00
		Min.	10.0	0.0
		Max.	100.0	100.0
Day 29	Impairment while working due to health (%)	n	10	18
		Mean	23.00	23.89
		SD	22.136	21.182
		Median	15.00	10.00
		Min.	10.0	0.0
		Max.	80.0	70.0
	Change from baseline in impairment while working due to health (%)	n	3	6
		Mean	-20.00	-25.00
		SD	34.641	35.071
		Median	0.00	-15.00
		Min.	-60.0	-90.0
		Max.	0.0	0.0

Note: WPAI was scheduled for the Expansion phase only.
PPD

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Overall work impairment due to health (%)	n	11	14
		Mean	67.56	54.08
		SD	30.030	33.722
		Median	76.67	71.00
		Min.	20.0	0.0
		Max.	100.0	100.0
Day 29	Overall work impairment due to health (%)	n	10	18
		Mean	23.98	28.16
		SD	22.133	23.393
		Median	18.14	18.33
		Min.	10.0	0.0
		Max.	80.0	81.1
	Change from baseline in overall work impairment due to health (%)	n	3	6
		Mean	-44.13	-19.49
		SD	38.656	46.632
		Median	-60.39	-16.97
		Min.	-72.0	-90.0
		Max.	0.0	44.6

Note: WPAI was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Activity impairment due to health (%)	n	25	34
		Mean	61.60	58.24
		SD	26.721	28.335
		Median	70.00	70.00
		Min.	10.0	0.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	26	38
		Mean	24.62	24.74
		SD	23.192	25.012
		Median	10.00	10.00
		Min.	0.0	0.0
		Max.	80.0	90.0
	Change from baseline in activity impairment due to health (%)	n	14	22
		Mean	-40.71	-35.91
		SD	29.211	30.025
		Median	-40.00	-40.00
		Min.	-90.0	-80.0
		Max.	0.0	20.0

Note: WPAI was scheduled for the Expansion phase only.
PPD

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		187	166
Baseline	Work time missed due to health (%)	n	79	75
		Mean	47.06	48.06
		SD	39.424	39.418
		Median	40.00	46.67
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Work time missed due to health (%)	n	46	41
		Mean	12.69	19.75
		SD	29.858	37.226
		Median	0.00	0.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from baseline in work time missed due to health (%)	n	34	32
		Mean	-35.00	-21.40
		SD	44.271	44.035
		Median	-33.96	0.00
		Min.	-100.0	-100.0
		Max.	100.0	64.3

Note: WPAI was scheduled for the Expansion phase only.
PPD

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Impairment while working due to health (%)	n	26	25
		Mean	53.08	32.80
		SD	32.957	29.654
		Median	55.00	20.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Impairment while working due to health (%)	n	34	23
		Mean	22.06	26.96
		SD	19.967	21.833
		Median	10.00	20.00
		Min.	0.0	0.0
		Max.	70.0	70.0
	Change from baseline in impairment while working due to health (%)	n	13	10
		Mean	-40.00	-6.00
		SD	36.742	21.187
		Median	-40.00	0.00
		Min.	-100.0	-50.0
		Max.	20.0	20.0

Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Overall work impairment due to health (%)	n	26	25
		Mean	65.71	51.76
		SD	30.217	34.273
		Median	71.50	61.43
		Min.	10.0	0.0
		Max.	100.0	100.0
Day 29	Overall work impairment due to health (%)	n	34	23
		Mean	25.85	31.37
		SD	23.054	27.683
		Median	20.00	25.58
		Min.	0.0	0.0
		Max.	73.0	87.5
	Change from baseline in overall work impairment due to health (%)	n	13	10
		Mean	-47.81	-15.15
		SD	38.482	25.325
		Median	-60.00	-18.18
		Min.	-100.0	-56.4
		Max.	20.0	21.4

Note: WPAI was scheduled for the Expansion phase only.
PPD

Table 214.4
Summary of Absolute and Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	Activity impairment due to health (%)	n	76	59
		Mean	59.34	45.25
		SD	30.081	30.814
		Median	70.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	Activity impairment due to health (%)	n	74	63
		Mean	28.11	27.78
		SD	27.829	27.027
		Median	15.00	20.00
		Min.	0.0	0.0
		Max.	100.0	90.0
	Change from baseline in activity impairment due to health (%)	n	40	36
		Mean	-35.00	-15.00
		SD	30.213	34.434
		Median	-35.00	-10.00
		Min.	-90.0	-70.0
		Max.	20.0	70.0

Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Work time missed due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
n	5	13
LS Mean (SE)	31.38 (12.075)	8.45 (7.468)
95% C.I.	(7.48, 55.28)	(-6.33, 23.23)
LS Mean Change from Baseline (SE)	-18.73 (12.075)	-41.66 (7.468)
95% C.I.	(-42.63, 5.16)	(-56.44, -26.88)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-22.93 (14.132)
95% C.I.		(-50.90, 5.04)
p-value		0.108
Corrected Hedge’s g (SE) [1]		-0.81 (0.543)
95% C.I.		(-1.88, 0.25)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Impairment while working due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	2	6
LS Mean (SE)	37.26 (14.252)	11.41 (8.425)
95% C.I.	(8.33, 66.19)	(-5.70, 28.51)
LS Mean Change from Baseline (SE)	-11.60 (14.252)	-37.46 (8.425)
95% C.I.	(-40.54, 17.33)	(-54.56, -20.35)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-25.85 (16.378)
95% C.I.		(-59.10, 7.40)
p-value		0.124
Corrected Hedge’s g (SE) [1]		-1.09 (0.861)
95% C.I.		(-2.78, 0.59)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	2	6
LS Mean (SE)	61.59 (15.818)	14.98 (9.353)
95% C.I.	(29.45, 93.74)	(-4.03, 33.98)
LS Mean Change from Baseline (SE)	1.92 (15.818)	-44.69 (9.353)
95% C.I.	(-30.22, 34.07)	(-63.70, -25.69)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-46.62 (18.228)
95% C.I.		(-83.66, -9.57)
p-value		0.016
Corrected Hedge’s g (SE) [1]		-1.78 (0.929)
95% C.I.		(-3.60, 0.05)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Activity impairment due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	24	27
LS Mean (SE)	28.03 (5.151)	19.14 (4.889)
95% C.I.	(17.88, 38.19)	(9.50, 28.78)
LS Mean Change from Baseline (SE)	-29.86 (5.151)	-38.76 (4.889)
95% C.I.	(-40.02, -19.71)	(-48.40, -29.12)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-8.90 (7.110)
95% C.I.		(-22.92, 5.12)
p-value		0.213
Corrected Hedge’s g (SE) [1]		-0.35 (0.283)
95% C.I.		(-0.90, 0.21)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Work time missed due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
n	6	7
LS Mean (SE)	39.29 (10.973)	-3.02 (10.307)
95% C.I.	(17.57, 61.01)	(-23.42, 17.38)
LS Mean Change from Baseline (SE)	-10.82 (10.973)	-53.13 (10.307)
95% C.I.	(-32.54, 10.90)	(-73.53, -32.73)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-42.31 (14.964)
95% C.I.		(-71.93, -12.70)
p-value		0.006
Corrected Hedge’s g (SE) [1]		-1.45 (0.625)
95% C.I.		(-2.68, -0.23)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI)
Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Impairment while working due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	0	0

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI)
Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	0	0

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Activity impairment due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	20	9
LS Mean (SE)	31.54 (5.643)	20.79 (8.452)
95% C.I.	(20.41, 42.66)	(4.13, 37.46)
LS Mean Change from Baseline (SE)	-26.36 (5.643)	-37.10 (8.452)
95% C.I.	(-37.49, -15.23)	(-53.77, -20.44)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-10.74 (10.150)
95% C.I.		(-30.75, 9.27)
p-value		0.292
Corrected Hedge’s g (SE) [1]		-0.41 (0.405)
95% C.I.		(-1.21, 0.38)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Work time missed due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
n	5	11
LS Mean (SE)	7.51 (12.045)	3.59 (8.120)
95% C.I.	(-16.33, 31.34)	(-12.48, 19.66)
LS Mean Change from Baseline (SE)	-42.61 (12.045)	-46.53 (8.120)
95% C.I.	(-66.45, -18.77)	(-62.60, -30.45)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-3.92 (14.583)
95% C.I.		(-32.78, 24.94)
p-value		0.789
Corrected Hedge’s g (SE) [1]		-0.14 (0.540)
95% C.I.		(-1.20, 0.92)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Impairment while working due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	1	3
LS Mean (SE)	51.44 (20.070)	18.80 (11.944)
95% C.I.	(10.70, 92.19)	(-5.44, 43.05)
LS Mean Change from Baseline (SE)	2.58 (20.070)	-30.06 (11.944)
95% C.I.	(-38.16, 43.33)	(-54.31, -5.81)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-32.64 (23.474)
95% C.I.		(-80.30, 15.01)
p-value		0.174
Corrected Hedge’s g (SE) [1]		-0.90 (1.198)
95% C.I.		(-3.25, 1.45)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	1	2
LS Mean (SE)	49.02 (22.307)	16.33 (16.153)
95% C.I.	(3.69, 94.35)	(-16.49, 49.16)
LS Mean Change from Baseline (SE)	-10.65 (22.307)	-43.34 (16.153)
95% C.I.	(-55.98, 34.69)	(-76.16, -10.51)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-32.69 (27.464)
95% C.I.		(-88.50, 23.12)
p-value		0.243
Corrected Hedge’s g (SE) [1]		0.00 (1.225)
95% C.I.		(-2.40, 2.40)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Activity impairment due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	13	14
LS Mean (SE)	37.22 (7.029)	22.74 (6.743)
95% C.I.	(23.36, 51.08)	(9.45, 36.03)
LS Mean Change from Baseline (SE)	-20.68 (7.029)	-35.16 (6.743)
95% C.I.	(-34.53, -6.82)	(-48.45, -21.87)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-14.48 (9.738)
95% C.I.		(-33.68, 4.71)
p-value		0.139
Corrected Hedge’s g (SE) [1]		-0.56 (0.393)
95% C.I.		(-1.32, 0.21)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Work time missed due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	62	77
n	8	15
LS Mean (SE)	1.34 (9.486)	6.05 (6.925)
95% C.I.	(-17.43, 20.12)	(-7.66, 19.75)
LS Mean Change from Baseline (SE)	-48.77 (9.486)	-44.06 (6.925)
95% C.I.	(-67.55, -30.00)	(-57.77, -30.36)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		4.71 (11.745)
95% C.I.		(-18.54, 27.95)
p-value		0.690
Corrected Hedge’s g (SE) [1]		0.17 (0.439)
95% C.I.		(-0.69, 1.03)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Impairment while working due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	3	6
LS Mean (SE)	15.86 (11.691)	27.61 (8.198)
95% C.I.	(-7.87, 39.60)	(10.96, 44.25)
LS Mean Change from Baseline (SE)	-33.00 (11.691)	-21.26 (8.198)
95% C.I.	(-56.73, -9.27)	(-37.90, -4.62)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		11.74 (14.334)
95% C.I.		(-17.36, 40.84)
p-value		0.419
Corrected Hedge’s g (SE) [1]		0.52 (0.718)
95% C.I.		(-0.89, 1.92)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	3	6
LS Mean (SE)	15.45 (12.874)	38.68 (9.106)
95% C.I.	(-10.72, 41.61)	(20.17, 57.18)
LS Mean Change from Baseline (SE)	-44.22 (12.874)	-20.99 (9.106)
95% C.I.	(-70.39, -18.06)	(-39.50, -2.49)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		23.23 (15.769)
95% C.I.		(-8.82, 55.28)
p-value		0.150
Corrected Hedge’s g (SE) [1]		0.93 (0.740)
95% C.I.		(-0.52, 2.38)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Activity impairment due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	14	22
LS Mean (SE)	25.97 (6.772)	24.84 (5.383)
95% C.I.	(12.61, 39.32)	(14.23, 35.45)
LS Mean Change from Baseline (SE)	-31.93 (6.772)	-33.06 (5.383)
95% C.I.	(-45.28, -18.58)	(-43.67, -22.45)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.13 (8.636)
95% C.I.		(-18.15, 15.90)
p-value		0.897
Corrected Hedge’s g (SE) [1]		-0.04 (0.342)
95% C.I.		(-0.71, 0.63)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI)
Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Work time missed due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
n	34	32
LS Mean (SE)	8.78 (4.618)	19.31 (4.781)
95% C.I.	(-0.36, 17.92)	(9.85, 28.77)
LS Mean Change from Baseline (SE)	-41.34 (4.618)	-30.80 (4.781)
95% C.I.	(-50.48, -32.20)	(-40.26, -21.34)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		10.53 (6.608)
95% C.I.		(-2.55, 23.61)
p-value		0.114
Corrected Hedge’s g (SE) [1]		0.39 (0.249)
95% C.I.		(-0.10, 0.87)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Impairment while working due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	13	10
LS Mean (SE)	21.40 (5.783)	33.77 (6.443)
95% C.I.	(9.67, 33.14)	(20.69, 46.85)
LS Mean Change from Baseline (SE)	-27.46 (5.783)	-15.09 (6.443)
95% C.I.	(-39.20, -15.72)	(-28.17, -2.01)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		12.37 (8.866)
95% C.I.		(-5.63, 30.37)
p-value		0.172
Corrected Hedge’s g (SE) [1]		0.58 (0.429)
95% C.I.		(-0.26, 1.42)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Overall work impairment due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	13	10
LS Mean (SE)	21.94 (6.324)	38.27 (7.099)
95% C.I.	(9.09, 34.79)	(23.84, 52.70)
LS Mean Change from Baseline (SE)	-37.73 (6.324)	-21.40 (7.099)
95% C.I.	(-50.58, -24.88)	(-35.83, -6.97)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		16.33 (9.621)
95% C.I.		(-3.22, 35.88)
p-value		0.099
Corrected Hedge’s g (SE) [1]		0.69 (0.433)
95% C.I.		(-0.15, 1.54)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.5
Analysis of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Activity impairment due to health (%)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	40	36
LS Mean (SE)	25.45 (3.993)	32.29 (4.274)
95% C.I.	(17.58, 33.32)	(23.86, 40.71)
LS Mean Change from Baseline (SE)	-32.45 (3.993)	-25.61 (4.274)
95% C.I.	(-40.32, -24.58)	(-34.04, -17.19)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		6.84 (5.873)
95% C.I.		(-4.74, 18.41)
p-value		0.246
Corrected Hedge’s g (SE) [1]		0.27 (0.231)
95% C.I.		(-0.19, 0.72)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: WPAI was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		97	101
Baseline	SF-12 Score	n	68	68
		Mean	49.13	54.78
		SD	35.172	34.081
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	41	44
		Mean	79.27	83.52
		SD	28.451	27.462
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	36	35
		Mean	28.03	28.57
		SD	38.933	31.590
		Median	25.00	25.00
		Min.	-50.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	41.05	42.82
		SD	11.072	10.729
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	41	44
		Mean	50.53	51.87
		SD	8.956	8.645
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	36	35
		Mean	8.82	8.99
		SD	12.256	9.944
		Median	7.87	7.87
		Min.	-15.7	-15.7
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	45.04	54.60
		SD	27.585	31.065
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	41	44
		Mean	70.12	85.23
		SD	26.499	21.274
		Median	75.00	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	36	35
		Mean	22.92	30.36
		SD	30.837	31.693
		Median	18.75	37.50
		Min.	-25.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	38.86	42.09
		SD	9.339	10.516
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	41	44
		Mean	47.35	52.46
		SD	8.969	7.200
		Median	49.00	57.46
		Min.	23.6	32.1
		Max.	57.5	57.5
	Change from Baseline	n	36	35
		Mean	7.76	10.28
		SD	10.438	10.728
		Median	6.35	12.70
		Min.	-8.5	-16.9
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	67	68
		Mean	60.07	58.09
		SD	25.023	32.450
		Median	50.00	50.00
		Min.	25.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	41	44
		Mean	81.10	80.68
		SD	23.572	29.464
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	36	35
		Mean	22.92	20.71
		SD	30.104	37.123
		Median	25.00	25.00
		Min.	-50.0	-75.0
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	67	68
		Mean	43.32	42.61
		SD	9.028	11.706
		Median	39.69	39.69
		Min.	30.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	41	44
		Mean	50.91	50.76
		SD	8.504	10.629
		Median	57.73	57.73
		Min.	21.7	21.7
		Max.	57.7	57.7
	Change from Baseline	n	36	35
		Mean	8.27	7.47
		SD	10.861	13.394
		Median	9.02	9.02
		Min.	-18.0	-27.1
		Max.	27.1	27.1

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	56.76	56.91
		SD	29.419	31.905
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	41	44
		Mean	66.34	69.09
		SD	22.777	21.493
		Median	60.00	60.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	36	35
		Mean	11.39	18.57
		SD	30.836	34.011
		Median	0.00	0.00
		Min.	-75.0	-60.0
		Max.	75.0	85.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	46.47	46.52
		SD	11.696	12.684
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	41	44
		Mean	50.27	51.37
		SD	9.055	8.545
		Median	47.75	47.75
		Min.	23.9	33.8
		Max.	63.7	63.7
	Change from Baseline	n	36	35
		Mean	4.53	7.38
		SD	12.259	13.520
		Median	0.00	0.00
		Min.	-29.8	-23.8
		Max.	29.8	33.8

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	43.75	41.54
		SD	27.104	31.030
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	41	44
		Mean	62.80	62.50
		SD	31.683	36.369
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	36	35
		Mean	18.06	10.00
		SD	37.612	48.583
		Median	25.00	25.00
		Min.	-75.0	-100.0
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	46.61	45.74
		SD	10.665	12.210
		Median	49.07	49.07
		Min.	29.4	29.4
		Max.	68.7	68.7
Day 29	SF-12 Score	n	41	44
		Mean	54.10	53.98
		SD	12.466	14.310
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	36	35
		Mean	7.10	3.93
		SD	14.799	19.116
		Median	9.83	9.83
		Min.	-29.5	-39.3
		Max.	29.5	29.5

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	51.47	48.53
		SD	34.252	37.127
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	41	44
		Mean	80.49	86.36
		SD	22.017	24.385
		Median	75.00	100.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	36	35
		Mean	33.33	37.86
		SD	37.796	36.568
		Median	50.00	50.00
		Min.	-50.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	39.63	38.59
		SD	12.186	13.210
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	41	44
		Mean	49.96	52.05
		SD	7.833	8.675
		Median	48.01	56.90
		Min.	30.2	21.3
		Max.	56.9	56.9
	Change from Baseline	n	36	35
		Mean	11.86	13.47
		SD	13.447	13.010
		Median	17.79	17.79
		Min.	-17.8	-26.7
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	58.82	61.95
		SD	28.575	29.959
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	41	44
		Mean	78.05	87.22
		SD	24.966	20.261
		Median	87.50	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	36	35
		Mean	19.44	25.00
		SD	32.382	26.430
		Median	25.00	25.00
		Min.	-50.0	-25.0
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	39.16	40.46
		SD	11.883	12.458
		Median	35.49	35.49
		Min.	14.7	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	41	44
		Mean	47.15	50.96
		SD	10.381	8.425
		Median	51.08	56.28
		Min.	14.7	25.1
		Max.	56.3	56.3
	Change from Baseline	n	36	35
		Mean	8.09	10.40
		SD	13.466	10.990
		Median	10.40	10.40
		Min.	-20.8	-10.4
		Max.	31.2	31.2

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	57.90	54.60
		SD	22.014	25.269
		Median	50.00	50.00
		Min.	12.5	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	41	44
		Mean	73.05	73.58
		SD	22.253	23.535
		Median	75.00	75.00
		Min.	12.5	25.0
		Max.	100.0	100.0
	Change from Baseline	n	36	35
		Mean	18.96	19.64
		SD	30.499	31.693
		Median	12.50	25.00
		Min.	-37.5	-50.0
		Max.	75.0	87.5

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	44.89	43.37
		SD	10.103	11.596
		Median	41.26	41.26
		Min.	24.1	18.3
		Max.	64.2	64.2
Day 29	SF-12 Score	n	41	44
		Mean	51.84	52.08
		SD	10.212	10.801
		Median	52.74	52.74
		Min.	24.1	29.8
		Max.	64.2	64.2
	Change from Baseline	n	36	35
		Mean	8.70	9.02
		SD	13.998	14.545
		Median	5.74	11.47
		Min.	-17.2	-23.0
		Max.	34.4	40.1

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Physical Component Summary

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	42.55	44.22
		SD	8.738	9.108
		Median	42.53	43.93
		Min.	25.5	23.0
		Max.	58.9	62.7
Day 29	SF-12 Score	n	41	44
		Mean	49.91	51.70
		SD	8.354	8.435
		Median	50.68	53.65
		Min.	27.1	29.8
		Max.	65.3	69.4
	Change from Baseline	n	36	35
		Mean	6.86	7.66
		SD	10.167	9.660
		Median	7.85	8.79
		Min.	-19.0	-13.6
		Max.	31.0	27.2

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Mental Component Summary

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	43.35	41.97
		SD	9.512	11.104
		Median	41.14	40.51
		Min.	19.3	16.3
		Max.	63.9	64.3
Day 29	SF-12 Score	n	41	44
		Mean	50.72	52.09
		SD	9.643	9.429
		Median	51.33	51.49
		Min.	28.7	20.4
		Max.	64.7	64.8
	Change from Baseline	n	36	35
		Mean	8.73	9.26
		SD	12.484	12.962
		Median	10.16	8.34
		Min.	-20.0	-16.6
		Max.	30.1	41.8

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Health Utility Index

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	67	68
		Mean	0.642	0.649
		SD	0.1197	0.1686
		Median	0.615	0.615
		Min.	0.43	0.35
		Max.	1.00	1.00
Day 29	SF-12 Score	n	41	44
		Mean	0.778	0.817
		SD	0.1519	0.1725
		Median	0.782	0.831
		Min.	0.42	0.43
		Max.	1.00	1.00
	Change from Baseline	n	36	35
		Mean	0.141	0.148
		SD	0.1885	0.1875
		Median	0.119	0.126
		Min.	-0.24	-0.29
		Max.	0.52	0.48

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	45.96	51.29
		SD	25.888	30.989
		Median	46.88	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	41	44
		Mean	73.48	86.08
		SD	22.043	21.092
		Median	75.00	100.00
		Min.	25.0	18.8
		Max.	100.0	100.0
	Change from Baseline	n	36	35
		Mean	25.35	33.93
		SD	29.766	29.947
		Median	18.75	37.50
		Min.	-18.8	-18.8
		Max.	93.8	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	37.74	39.65
		SD	9.302	11.134
		Median	38.07	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 29	SF-12 Score	n	41	44
		Mean	47.63	52.16
		SD	7.921	7.580
		Median	48.17	57.16
		Min.	30.2	28.0
		Max.	57.2	57.2
	Change from Baseline	n	36	35
		Mean	9.11	12.19
		SD	10.696	10.761
		Median	6.74	13.48
		Min.	-6.7	-6.7
		Max.	33.7	35.9

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	46.14	41.82
		SD	22.703	28.205
		Median	50.00	46.88
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	41	44
		Mean	67.99	72.02
		SD	22.887	28.290
		Median	62.50	78.13
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	36	35
		Mean	21.70	24.11
		SD	29.448	32.868
		Median	18.75	31.25
		Min.	-25.0	-56.3
		Max.	81.3	87.5

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	68	68
		Mean	44.82	42.77
		SD	10.792	13.407
		Median	46.66	45.18
		Min.	22.9	22.9
		Max.	70.4	70.4
Day 29	SF-12 Score	n	41	44
		Mean	55.21	57.12
		SD	10.876	13.445
		Median	52.60	60.03
		Min.	34.8	22.9
		Max.	70.4	70.4
	Change from Baseline	n	36	35
		Mean	10.31	11.46
		SD	13.996	15.622
		Median	8.91	14.85
		Min.	-11.9	-26.7
		Max.	38.6	41.6

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		87	76
Baseline	SF-12 Score	n	63	64
		Mean	50.79	57.03
		SD	32.056	32.874
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	47	36
		Mean	78.72	82.64
		SD	27.076	30.366
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	41	32
		Mean	24.39	35.94
		SD	38.523	40.130
		Median	25.00	50.00
		Min.	-75.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	41.57	43.53
		SD	10.091	10.349
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	47	36
		Mean	50.36	51.59
		SD	8.524	9.559
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	41	32
		Mean	7.68	11.31
		SD	12.127	12.633
		Median	7.87	15.74
		Min.	-23.6	-31.5
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	46.63	46.29
		SD	24.920	26.882
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	47	36
		Mean	77.39	78.47
		SD	22.061	30.415
		Median	75.00	100.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	41	32
		Mean	26.83	36.72
		SD	26.599	37.424
		Median	25.00	50.00
		Min.	-12.5	-62.5
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	39.40	39.28
		SD	8.437	9.100
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	47	36
		Mean	49.81	50.17
		SD	7.467	10.296
		Median	49.00	57.46
		Min.	32.1	23.6
		Max.	57.5	57.5
	Change from Baseline	n	41	32
		Mean	9.08	12.43
		SD	9.004	12.668
		Median	8.46	16.92
		Min.	-4.2	-21.2
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	57.14	58.20
		SD	28.195	31.198
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	47	36
		Mean	82.45	93.75
		SD	23.840	16.229
		Median	100.00	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	41	32
		Mean	19.51	42.19
		SD	32.361	30.079
		Median	25.00	50.00
		Min.	-100.0	-25.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	42.27	42.65
		SD	10.171	11.254
		Median	39.69	39.69
		Min.	21.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	47	36
		Mean	51.40	55.48
		SD	8.601	5.856
		Median	57.73	57.73
		Min.	21.7	30.7
		Max.	57.7	57.7
	Change from Baseline	n	41	32
		Mean	7.04	15.22
		SD	11.675	10.851
		Median	9.02	18.04
		Min.	-36.1	-9.0
		Max.	27.1	36.1

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	51.27	50.16
		SD	29.770	30.693
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	47	36
		Mean	69.79	66.81
		SD	18.296	21.881
		Median	60.00	60.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	41	32
		Mean	15.00	17.97
		SD	22.444	39.592
		Median	0.00	0.00
		Min.	-40.0	-100.0
		Max.	75.0	85.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	44.28	43.84
		SD	11.835	12.202
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	47	36
		Mean	51.64	50.46
		SD	7.275	8.700
		Median	47.75	47.75
		Min.	33.8	23.9
		Max.	63.7	63.7
	Change from Baseline	n	41	32
		Mean	5.96	7.14
		SD	8.923	15.740
		Median	0.00	0.00
		Min.	-15.9	-39.8
		Max.	29.8	33.8

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	40.48	39.06
		SD	28.901	31.458
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	47	35
		Mean	72.34	77.86
		SD	25.127	33.084
		Median	75.00	100.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	41	32
		Mean	26.83	39.84
		SD	35.085	40.590
		Median	25.00	50.00
		Min.	-50.0	-100.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	45.32	44.76
		SD	11.372	12.379
		Median	49.07	49.07
		Min.	29.4	29.4
		Max.	68.7	68.7
Day 29	SF-12 Score	n	47	35
		Mean	57.86	60.03
		SD	9.886	13.018
		Median	58.90	68.74
		Min.	39.2	29.4
		Max.	68.7	68.7
	Change from Baseline	n	41	32
		Mean	10.56	15.68
		SD	13.804	15.971
		Median	9.84	19.67
		Min.	-19.7	-39.3
		Max.	29.5	39.3

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	42.86	42.19
		SD	29.590	32.390
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	47	36
		Mean	78.72	84.72
		SD	24.988	28.207
		Median	75.00	100.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	41	32
		Mean	30.49	43.75
		SD	31.875	43.068
		Median	25.00	50.00
		Min.	-25.0	-75.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	36.57	36.33
		SD	10.528	11.525
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	47	36
		Mean	49.33	51.47
		SD	8.890	10.036
		Median	48.01	56.90
		Min.	30.2	21.3
		Max.	56.9	56.9
	Change from Baseline	n	41	32
		Mean	10.85	15.57
		SD	11.341	15.324
		Median	8.90	17.79
		Min.	-8.9	-26.7
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	57.94	58.20
		SD	27.524	29.565
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	47	36
		Mean	81.65	81.94
		SD	21.784	29.947
		Median	100.00	100.00
		Min.	37.5	0.0
		Max.	100.0	100.0
	Change from Baseline	n	41	32
		Mean	22.26	31.64
		SD	27.601	39.013
		Median	12.50	50.00
		Min.	-12.5	-62.5
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	38.79	38.90
		SD	11.445	12.294
		Median	35.49	35.49
		Min.	14.7	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	47	36
		Mean	48.65	48.77
		SD	9.057	12.452
		Median	56.28	56.28
		Min.	30.3	14.7
		Max.	56.3	56.3
	Change from Baseline	n	41	32
		Mean	9.25	13.16
		SD	11.477	16.222
		Median	5.20	20.79
		Min.	-5.2	-26.0
		Max.	41.6	41.6

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	52.38	53.91
		SD	23.316	20.397
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	47	36
		Mean	80.32	77.78
		SD	19.634	23.925
		Median	87.50	87.50
		Min.	37.5	12.5
		Max.	100.0	100.0
	Change from Baseline	n	41	32
		Mean	24.39	28.91
		SD	24.036	30.526
		Median	25.00	37.50
		Min.	-37.5	-25.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	42.36	43.06
		SD	10.700	9.361
		Median	41.26	41.26
		Min.	18.3	18.3
		Max.	64.2	64.2
Day 29	SF-12 Score	n	47	36
		Mean	55.18	54.01
		SD	9.011	10.980
		Median	58.47	58.47
		Min.	35.5	24.1
		Max.	64.2	64.2
	Change from Baseline	n	41	32
		Mean	11.19	13.27
		SD	11.032	14.010
		Median	11.47	17.21
		Min.	-17.2	-11.5
		Max.	34.4	45.9

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Physical Component Summary

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	42.63	43.24
		SD	8.792	8.556
		Median	41.84	43.93
		Min.	21.5	22.4
		Max.	60.5	61.0
Day 29	SF-12 Score	n	47	36
		Mean	50.29	52.20
		SD	6.730	6.609
		Median	51.15	53.65
		Min.	25.0	23.6
		Max.	59.7	60.2
	Change from Baseline	n	41	32
		Mean	6.14	10.66
		SD	9.738	9.246
		Median	5.82	11.23
		Min.	-30.1	-19.7
		Max.	26.0	28.8

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Mental Component Summary

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	40.80	40.52
		SD	10.605	9.838
		Median	40.51	40.51
		Min.	14.3	11.0
		Max.	73.0	63.5
Day 29	SF-12 Score	n	47	36
		Mean	53.38	53.10
		SD	9.593	10.285
		Median	54.99	55.60
		Min.	34.0	29.8
		Max.	65.6	64.7
	Change from Baseline	n	41	32
		Mean	11.19	14.30
		SD	11.797	13.856
		Median	9.97	17.83
		Min.	-12.9	-16.0
		Max.	34.1	43.7

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Health Utility Index

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	0.616	0.617
		SD	0.1248	0.1188
		Median	0.615	0.615
		Min.	0.35	0.35
		Max.	1.00	1.00
Day 29	SF-12 Score	n	47	35
		Mean	0.796	0.858
		SD	0.1602	0.1602
		Median	0.800	0.922
		Min.	0.52	0.48
		Max.	1.00	1.00
	Change from Baseline	n	41	32
		Mean	0.155	0.266
		SD	0.1643	0.2076
		Median	0.107	0.332
		Min.	-0.14	-0.31
		Max.	0.47	0.66

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	45.04	44.73
		SD	24.132	25.954
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	47	36
		Mean	78.46	80.90
		SD	19.233	28.736
		Median	75.00	100.00
		Min.	37.5	6.3
		Max.	100.0	100.0
	Change from Baseline	n	41	32
		Mean	28.05	41.21
		SD	24.372	35.670
		Median	25.00	50.00
		Min.	-25.0	-56.3
		Max.	87.5	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	37.41	37.30
		SD	8.670	9.325
		Median	39.19	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 29	SF-12 Score	n	47	36
		Mean	49.42	50.30
		SD	6.912	10.325
		Median	48.17	57.16
		Min.	34.7	23.5
		Max.	57.2	57.2
	Change from Baseline	n	41	32
		Mean	10.08	14.81
		SD	8.757	12.816
		Median	8.98	17.96
		Min.	-9.0	-20.2
		Max.	31.4	35.9

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	42.76	41.02
		SD	22.003	26.373
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	93.8	100.0
Day 29	SF-12 Score	n	47	36
		Mean	76.60	78.70
		SD	20.952	25.859
		Median	81.25	90.63
		Min.	37.5	12.5
		Max.	100.0	100.0
	Change from Baseline	n	41	32
		Mean	29.73	38.28
		SD	26.729	31.819
		Median	25.00	46.88
		Min.	-31.3	-43.8
		Max.	81.3	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	63	64
		Mean	43.22	42.39
		SD	10.460	12.536
		Median	46.66	46.66
		Min.	22.9	22.9
		Max.	67.5	70.4
Day 29	SF-12 Score	n	47	36
		Mean	59.30	60.30
		SD	9.956	12.290
		Median	61.51	65.97
		Min.	40.7	28.8
		Max.	70.4	70.4
	Change from Baseline	n	41	32
		Mean	14.13	18.19
		SD	12.704	15.123
		Median	11.88	22.28
		Min.	-14.9	-20.8
		Max.	38.6	47.5

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		58	64
Baseline	SF-12 Score	n	47	50
		Mean	60.11	56.00
		SD	31.562	27.461
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	37	34
		Mean	83.11	86.76
		SD	24.334	24.799
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	34	32
		Mean	22.06	33.59
		SD	34.687	32.756
		Median	0.00	50.00
		Min.	-25.0	-25.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	44.50	43.21
		SD	9.936	8.645
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	37	34
		Mean	51.74	52.89
		SD	7.660	7.807
		Median	57.06	57.06
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	34	32
		Mean	6.94	10.58
		SD	10.920	10.312
		Median	0.00	15.74
		Min.	-7.9	-7.9
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	52.39	50.50
		SD	26.017	28.789
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	37	34
		Mean	78.04	85.29
		SD	28.014	22.502
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	34	32
		Mean	28.68	35.94
		SD	37.881	35.462
		Median	25.00	43.75
		Min.	-50.0	-25.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	41.35	40.71
		SD	8.807	9.746
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	37	34
		Mean	50.03	52.48
		SD	9.482	7.616
		Median	57.46	57.46
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	34	32
		Mean	9.71	12.16
		SD	12.823	12.004
		Median	8.47	14.81
		Min.	-16.9	-8.5
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	67.55	61.22
		SD	26.537	27.510
		Median	75.00	75.00
		Min.	25.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	37	34
		Mean	85.81	92.65
		SD	25.373	16.888
		Median	100.00	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	34	31
		Mean	19.85	33.06
		SD	32.438	29.852
		Median	25.00	25.00
		Min.	-50.0	-25.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	46.02	43.74
		SD	9.575	9.925
		Median	48.71	48.71
		Min.	30.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	37	34
		Mean	52.61	55.08
		SD	9.153	6.093
		Median	57.73	57.73
		Min.	21.7	30.7
		Max.	57.7	57.7
	Change from Baseline	n	34	31
		Mean	7.16	11.93
		SD	11.703	10.770
		Median	9.02	9.02
		Min.	-18.0	-9.0
		Max.	27.1	36.1

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	56.38	49.90
		SD	23.927	28.953
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	37	34
		Mean	72.57	64.41
		SD	17.385	19.139
		Median	60.00	60.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	34	32
		Mean	16.76	14.69
		SD	25.132	30.925
		Median	15.00	0.00
		Min.	-35.0	-60.0
		Max.	85.0	85.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	46.31	43.74
		SD	9.512	11.510
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	37	34
		Mean	52.75	49.51
		SD	6.913	7.610
		Median	47.75	47.75
		Min.	33.8	23.9
		Max.	63.7	63.7
	Change from Baseline	n	34	32
		Mean	6.67	5.84
		SD	9.991	12.294
		Median	5.97	0.00
		Min.	-13.9	-23.9
		Max.	33.8	33.8

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	37.77	32.00
		SD	27.023	25.274
		Median	50.00	25.00
		Min.	0.0	0.0
		Max.	100.0	75.0
Day 29	SF-12 Score	n	37	34
		Mean	65.54	67.65
		SD	34.030	34.559
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	34	32
		Mean	27.94	36.72
		SD	33.578	34.771
		Median	25.00	25.00
		Min.	-50.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	44.25	41.98
		SD	10.634	9.946
		Median	49.07	39.23
		Min.	29.4	29.4
		Max.	68.7	58.9
Day 29	SF-12 Score	n	37	34
		Mean	55.18	56.01
		SD	13.390	13.598
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	34	32
		Mean	10.99	14.45
		SD	13.213	13.682
		Median	9.84	9.84
		Min.	-19.7	-19.7
		Max.	39.3	39.3

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	51.60	49.00
		SD	33.135	33.866
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	37	34
		Mean	83.11	85.29
		SD	27.672	28.283
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	34	32
		Mean	33.82	32.03
		SD	39.830	37.693
		Median	50.00	25.00
		Min.	-50.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	39.68	38.76
		SD	11.790	12.050
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	37	34
		Mean	50.89	51.67
		SD	9.845	10.062
		Median	56.90	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	34	32
		Mean	12.03	11.40
		SD	14.171	13.411
		Median	17.79	8.90
		Min.	-17.8	-17.8
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	63.79	64.00
		SD	23.133	23.776
		Median	50.00	62.50
		Min.	12.5	12.5
		Max.	100.0	100.0
Day 29	SF-12 Score	n	37	34
		Mean	84.46	89.34
		SD	26.088	21.127
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	34	32
		Mean	24.33	27.34
		SD	29.936	31.819
		Median	31.25	25.00
		Min.	-25.0	-37.5
		Max.	87.5	87.5

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	41.22	41.31
		SD	9.620	9.887
		Median	35.49	40.69
		Min.	19.9	19.9
		Max.	56.3	56.3
Day 29	SF-12 Score	n	37	34
		Mean	49.82	51.85
		SD	10.848	8.784
		Median	56.28	56.28
		Min.	14.7	14.7
		Max.	56.3	56.3
	Change from Baseline	n	34	32
		Mean	10.11	11.37
		SD	12.448	13.231
		Median	13.00	10.40
		Min.	-10.4	-15.6
		Max.	36.4	36.4

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	59.57	56.25
		SD	18.098	25.908
		Median	50.00	50.00
		Min.	25.0	12.5
		Max.	100.0	100.0
Day 29	SF-12 Score	n	37	34
		Mean	76.35	79.04
		SD	25.308	26.242
		Median	87.50	87.50
		Min.	12.5	0.0
		Max.	100.0	100.0
	Change from Baseline	n	34	32
		Mean	19.12	28.52
		SD	28.075	28.616
		Median	12.50	25.00
		Min.	-25.0	-37.5
		Max.	75.0	87.5

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	45.66	44.13
		SD	8.306	11.889
		Median	41.26	41.26
		Min.	29.8	24.1
		Max.	64.2	64.2
Day 29	SF-12 Score	n	37	34
		Mean	53.36	54.59
		SD	11.614	12.043
		Median	58.47	58.47
		Min.	24.1	18.3
		Max.	64.2	64.2
	Change from Baseline	n	34	32
		Mean	8.77	13.09
		SD	12.884	13.133
		Median	5.74	11.47
		Min.	-11.5	-17.2
		Max.	34.4	40.1

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Physical Component Summary

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	45.00	43.06
		SD	8.232	8.955
		Median	44.75	43.93
		Min.	18.0	26.6
		Max.	58.2	61.9
Day 29	SF-12 Score	n	37	34
		Mean	51.70	52.38
		SD	6.034	7.384
		Median	53.04	53.65
		Min.	38.6	26.1
		Max.	61.7	59.9
	Change from Baseline	n	34	32
		Mean	6.64	9.38
		SD	7.539	8.867
		Median	4.54	9.29
		Min.	-8.0	-6.0
		Max.	24.9	25.1

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Mental Component Summary

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	42.73	41.90
		SD	8.831	9.822
		Median	42.77	40.51
		Min.	17.2	23.8
		Max.	63.0	65.4
Day 29	SF-12 Score	n	37	34
		Mean	52.31	53.44
		SD	11.657	11.066
		Median	55.74	56.06
		Min.	16.0	16.8
		Max.	64.7	66.8
	Change from Baseline	n	34	32
		Mean	10.88	12.53
		SD	12.670	12.303
		Median	7.27	12.59
		Min.	-8.5	-9.7
		Max.	45.3	38.6

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Health Utility Index

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	49
		Mean	0.649	0.629
		SD	0.1076	0.1042
		Median	0.615	0.615
		Min.	0.47	0.37
		Max.	1.00	0.92
Day 29	SF-12 Score	n	37	34
		Mean	0.821	0.847
		SD	0.1698	0.1523
		Median	0.859	0.897
		Min.	0.41	0.48
		Max.	1.00	1.00
	Change from Baseline	n	34	31
		Mean	0.186	0.237
		SD	0.1859	0.1800
		Median	0.179	0.262
		Min.	-0.13	-0.06
		Max.	0.52	0.63

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	52.26	46.38
		SD	25.485	26.519
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	37	34
		Mean	80.74	85.66
		SD	25.743	22.166
		Median	93.75	93.75
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	34	32
		Mean	32.35	38.67
		SD	32.909	34.322
		Median	37.50	46.88
		Min.	-31.3	-31.3
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	40.00	37.89
		SD	9.155	9.528
		Median	39.19	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 29	SF-12 Score	n	37	34
		Mean	50.24	52.01
		SD	9.250	7.965
		Median	54.91	54.91
		Min.	21.2	21.2
		Max.	57.2	57.2
	Change from Baseline	n	34	32
		Mean	11.63	13.90
		SD	11.824	12.333
		Median	13.47	16.84
		Min.	-11.2	-11.2
		Max.	35.9	35.9

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	43.22	39.25
		SD	23.989	23.421
		Median	50.00	43.75
		Min.	0.0	0.0
		Max.	100.0	93.8
Day 29	SF-12 Score	n	37	34
		Mean	72.13	74.45
		SD	25.962	28.677
		Median	75.00	75.00
		Min.	12.5	0.0
		Max.	100.0	100.0
	Change from Baseline	n	34	32
		Mean	29.41	39.06
		SD	27.026	31.790
		Median	28.13	40.63
		Min.	-18.8	-12.5
		Max.	93.8	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	47	50
		Mean	43.43	41.55
		SD	11.403	11.134
		Median	46.66	43.69
		Min.	22.9	22.9
		Max.	70.4	67.5
Day 29	SF-12 Score	n	37	34
		Mean	57.17	58.28
		SD	12.339	13.630
		Median	58.54	58.54
		Min.	28.8	22.9
		Max.	70.4	70.4
	Change from Baseline	n	34	32
		Mean	13.98	18.57
		SD	12.846	15.110
		Median	13.37	19.31
		Min.	-8.9	-5.9
		Max.	44.6	47.5

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		62	77
Baseline	SF-12 Score	n	45	63
		Mean	57.78	59.92
		SD	33.635	32.235
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	35	46
		Mean	84.29	83.15
		SD	22.756	28.894
		Median	100.00	100.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	26	44
		Mean	27.88	20.45
		SD	32.655	33.355
		Median	25.00	0.00
		Min.	-25.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	43.77	44.44
		SD	10.588	10.148
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	35	46
		Mean	52.11	51.76
		SD	7.164	9.096
		Median	57.06	57.06
		Min.	33.5	25.6
		Max.	57.1	57.1
	Change from Baseline	n	26	44
		Mean	8.78	6.44
		SD	10.280	10.500
		Median	7.87	0.00
		Min.	-7.9	-15.7
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	53.06	52.98
		SD	29.695	26.914
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	35	46
		Mean	78.93	80.71
		SD	21.172	27.222
		Median	75.00	100.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	26	44
		Mean	30.77	25.85
		SD	28.114	33.061
		Median	25.00	25.00
		Min.	-12.5	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	41.57	41.54
		SD	10.053	9.111
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	35	46
		Mean	50.33	50.93
		SD	7.165	9.214
		Median	49.00	57.46
		Min.	32.1	23.6
		Max.	57.5	57.5
	Change from Baseline	n	26	44
		Mean	10.42	8.75
		SD	9.517	11.192
		Median	8.46	8.46
		Min.	-4.2	-16.9
		Max.	33.9	33.9

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	68.89	59.52
		SD	31.150	32.512
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	35	46
		Mean	95.71	88.59
		SD	11.320	21.542
		Median	100.00	100.00
		Min.	50.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	26	44
		Mean	34.62	27.27
		SD	32.463	29.442
		Median	37.50	25.00
		Min.	0.0	-50.0
		Max.	100.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	46.51	43.13
		SD	11.238	11.729
		Median	48.71	48.71
		Min.	21.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	35	46
		Mean	56.18	53.61
		SD	4.084	7.772
		Median	57.73	57.73
		Min.	39.7	30.7
		Max.	57.7	57.7
	Change from Baseline	n	26	44
		Mean	12.49	9.84
		SD	11.712	10.622
		Median	13.53	9.02
		Min.	0.0	-18.0
		Max.	36.1	27.1

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	44	63
		Mean	58.41	48.97
		SD	28.053	28.301
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	35	46
		Mean	78.57	68.48
		SD	18.533	22.133
		Median	85.00	60.00
		Min.	25.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	26	44
		Mean	17.69	18.98
		SD	27.358	29.405
		Median	0.00	12.50
		Min.	-25.0	-40.0
		Max.	85.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	44	63
		Mean	47.12	43.37
		SD	11.152	11.251
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	35	46
		Mean	55.14	51.12
		SD	7.370	8.800
		Median	57.69	47.75
		Min.	33.8	23.9
		Max.	63.7	63.7
	Change from Baseline	n	26	44
		Mean	7.03	7.54
		SD	10.877	11.690
		Median	0.00	4.97
		Min.	-9.9	-15.9
		Max.	33.8	29.8

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	35.00	34.52
		SD	25.783	25.172
		Median	25.00	25.00
		Min.	0.0	0.0
		Max.	100.0	75.0
Day 29	SF-12 Score	n	35	46
		Mean	56.43	66.85
		SD	31.121	31.205
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	26	44
		Mean	24.04	31.25
		SD	35.694	34.153
		Median	25.00	25.00
		Min.	-50.0	-50.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	43.16	42.98
		SD	10.146	9.905
		Median	39.23	39.23
		Min.	29.4	29.4
		Max.	68.7	58.9
Day 29	SF-12 Score	n	35	46
		Mean	51.59	55.70
		SD	12.245	12.278
		Median	58.90	58.90
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	26	44
		Mean	9.46	12.30
		SD	14.046	13.438
		Median	9.84	9.84
		Min.	-19.7	-19.7
		Max.	29.5	39.3

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	48.89	44.44
		SD	37.672	37.686
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	35	46
		Mean	86.43	87.50
		SD	21.302	21.570
		Median	100.00	100.00
		Min.	25.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	26	44
		Mean	32.69	43.18
		SD	40.478	38.263
		Median	37.50	50.00
		Min.	-25.0	-25.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	38.72	37.13
		SD	13.404	13.409
		Median	39.11	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	35	46
		Mean	52.07	52.45
		SD	7.578	7.674
		Median	56.90	56.90
		Min.	30.2	30.2
		Max.	56.9	56.9
	Change from Baseline	n	26	44
		Mean	11.63	15.36
		SD	14.402	13.613
		Median	13.35	17.79
		Min.	-8.9	-8.9
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	73.89	73.61
		SD	28.307	29.539
		Median	87.50	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	35	46
		Mean	91.43	86.68
		SD	12.780	20.983
		Median	100.00	100.00
		Min.	50.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	26	44
		Mean	16.35	13.64
		SD	24.690	31.185
		Median	6.25	0.00
		Min.	-25.0	-50.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	45.42	45.31
		SD	11.771	12.283
		Median	51.08	45.89
		Min.	14.7	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	35	46
		Mean	52.72	50.74
		SD	5.313	8.725
		Median	56.28	56.28
		Min.	35.5	25.1
		Max.	56.3	56.3
	Change from Baseline	n	26	44
		Mean	6.80	5.67
		SD	10.267	12.968
		Median	2.60	0.00
		Min.	-10.4	-20.8
		Max.	31.2	41.6

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	61.11	62.30
		SD	25.314	25.350
		Median	50.00	62.50
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	35	46
		Mean	75.36	80.71
		SD	21.327	18.765
		Median	75.00	87.50
		Min.	37.5	37.5
		Max.	100.0	100.0
	Change from Baseline	n	26	44
		Mean	16.83	20.17
		SD	28.272	28.684
		Median	12.50	12.50
		Min.	-37.5	-25.0
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	46.36	46.91
		SD	11.617	11.633
		Median	41.26	47.00
		Min.	18.3	18.3
		Max.	64.2	64.2
Day 29	SF-12 Score	n	35	46
		Mean	52.90	55.36
		SD	9.788	8.612
		Median	52.74	58.47
		Min.	35.5	35.5
		Max.	64.2	64.2
	Change from Baseline	n	26	44
		Mean	7.72	9.26
		SD	12.975	13.163
		Median	5.73	5.74
		Min.	-17.2	-11.5
		Max.	34.4	34.4

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Physical Component Summary

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	44.14	42.31
		SD	9.404	8.825
		Median	44.65	43.53
		Min.	18.8	20.4
		Max.	60.4	61.6
Day 29	SF-12 Score	n	35	46
		Mean	53.12	51.32
		SD	6.946	7.800
		Median	54.66	53.65
		Min.	35.1	27.7
		Max.	63.4	61.6
	Change from Baseline	n	26	44
		Mean	10.27	7.92
		SD	9.160	8.700
		Median	7.81	8.04
		Min.	-4.9	-15.0
		Max.	35.6	30.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Mental Component Summary

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	44.46	44.44
		SD	10.273	11.058
		Median	43.71	45.15
		Min.	17.5	15.8
		Max.	63.3	63.9
Day 29	SF-12 Score	n	35	46
		Mean	52.31	54.04
		SD	7.391	7.981
		Median	51.89	55.89
		Min.	35.4	30.7
		Max.	64.5	62.6
	Change from Baseline	n	26	44
		Mean	7.43	10.35
		SD	10.416	12.428
		Median	5.18	8.71
		Min.	-11.5	-15.3
		Max.	32.7	41.5

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Health Utility Index

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	0.662	0.641
		SD	0.1216	0.1278
		Median	0.657	0.630
		Min.	0.41	0.35
		Max.	1.00	0.92
Day 29	SF-12 Score	n	35	46
		Mean	0.803	0.831
		SD	0.1063	0.1529
		Median	0.817	0.863
		Min.	0.59	0.51
		Max.	0.94	1.00
	Change from Baseline	n	26	44
		Mean	0.165	0.186
		SD	0.1155	0.1817
		Median	0.147	0.191
		Min.	-0.08	-0.14
		Max.	0.36	0.55

Note: SF-12 was scheduled for the Expansion phase only.

PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	51.67	50.40
		SD	28.931	26.347
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	35	46
		Mean	81.43	82.20
		SD	19.966	23.458
		Median	87.50	100.00
		Min.	25.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	26	44
		Mean	32.45	30.68
		SD	28.064	29.433
		Median	25.00	34.38
		Min.	-18.8	-37.5
		Max.	87.5	93.8

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	39.79	39.33
		SD	10.394	9.465
		Median	39.19	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 29	SF-12 Score	n	35	46
		Mean	50.48	50.76
		SD	7.175	8.429
		Median	52.66	57.16
		Min.	30.2	30.2
		Max.	57.2	57.2
	Change from Baseline	n	26	44
		Mean	11.66	11.03
		SD	10.081	10.574
		Median	8.99	12.35
		Min.	-6.7	-13.5
		Max.	31.4	33.7

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	40.42	41.17
		SD	26.064	21.611
		Median	43.75	43.75
		Min.	0.0	0.0
		Max.	100.0	81.3
Day 29	SF-12 Score	n	35	46
		Mean	68.21	72.01
		SD	21.934	22.964
		Median	75.00	68.75
		Min.	18.8	18.8
		Max.	100.0	100.0
	Change from Baseline	n	26	44
		Mean	32.93	31.53
		SD	25.221	24.447
		Median	34.38	34.38
		Min.	-18.8	-25.0
		Max.	75.0	75.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	45	63
		Mean	42.10	42.46
		SD	12.390	10.273
		Median	43.69	43.69
		Min.	22.9	22.9
		Max.	70.4	61.5
Day 29	SF-12 Score	n	35	46
		Mean	55.31	57.12
		SD	10.425	10.914
		Median	58.54	55.57
		Min.	31.8	31.8
		Max.	70.4	70.4
	Change from Baseline	n	26	44
		Mean	15.65	14.99
		SD	11.988	11.621
		Median	16.34	16.34
		Min.	-8.9	-11.9
		Max.	35.7	35.7

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Physical Functioning (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
	Number of subjects in subgroup		187	166
Baseline	SF-12 Score	n	150	136
		Mean	59.67	58.09
		SD	33.999	36.373
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	90
		Mean	76.24	74.44
		SD	28.146	30.441
		Median	100.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	88	83
		Mean	10.23	12.65
		SD	35.281	38.725
		Median	0.00	0.00
		Min.	-75.0	-100.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Physical Functioning (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	44.36	43.87
		SD	10.703	11.450
		Median	41.32	41.32
		Min.	25.6	25.6
		Max.	57.1	57.1
Day 29	SF-12 Score	n	101	90
		Mean	49.58	49.02
		SD	8.860	9.583
		Median	57.06	49.19
		Min.	25.6	25.6
		Max.	57.1	57.1
	Change from Baseline	n	88	83
		Mean	3.22	3.98
		SD	11.107	12.191
		Median	0.00	0.00
		Min.	-23.6	-31.5
		Max.	31.5	31.5

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Physical (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	51.08	52.30
		SD	28.154	29.353
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	90
		Mean	76.61	76.25
		SD	25.658	26.437
		Median	75.00	87.50
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	88	83
		Mean	25.00	22.44
		SD	30.852	30.038
		Median	25.00	12.50
		Min.	-50.0	-50.0
		Max.	87.5	87.5

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Physical (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	40.90	41.31
		SD	9.531	9.937
		Median	40.54	40.54
		Min.	23.6	23.6
		Max.	57.5	57.5
Day 29	SF-12 Score	n	101	90
		Mean	49.54	49.42
		SD	8.685	8.949
		Median	49.00	53.23
		Min.	23.6	23.6
		Max.	57.5	57.5
	Change from Baseline	n	88	83
		Mean	8.46	7.60
		SD	10.444	10.169
		Median	8.46	4.24
		Min.	-16.9	-16.9
		Max.	29.6	29.6

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Bodily Pain (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	62.17	63.79
		SD	31.025	29.158
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	90
		Mean	85.40	87.50
		SD	21.583	20.950
		Median	100.00	100.00
		Min.	0.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	88	83
		Mean	21.88	21.99
		SD	30.279	29.836
		Median	25.00	25.00
		Min.	-50.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Bodily Pain (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	44.08	44.66
		SD	11.193	10.519
		Median	48.71	48.71
		Min.	21.7	21.7
		Max.	57.7	57.7
Day 29	SF-12 Score	n	101	90
		Mean	52.46	53.22
		SD	7.787	7.559
		Median	57.73	57.73
		Min.	21.7	30.7
		Max.	57.7	57.7
	Change from Baseline	n	88	83
		Mean	7.89	7.93
		SD	10.924	10.764
		Median	9.02	9.02
		Min.	-18.0	-18.0
		Max.	36.1	36.1

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: General Health (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	56.03	57.46
		SD	27.351	29.338
		Median	60.00	60.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	90
		Mean	70.35	69.28
		SD	22.386	20.671
		Median	60.00	60.00
		Min.	25.0	25.0
		Max.	100.0	100.0
	Change from Baseline	n	88	83
		Mean	14.09	9.40
		SD	29.852	30.488
		Median	0.00	0.00
		Min.	-60.0	-40.0
		Max.	85.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: General Health (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	46.18	46.74
		SD	10.873	11.663
		Median	47.75	47.75
		Min.	23.9	23.9
		Max.	63.7	63.7
Day 29	SF-12 Score	n	101	90
		Mean	51.87	51.44
		SD	8.900	8.218
		Median	47.75	47.75
		Min.	33.8	33.8
		Max.	63.7	63.7
	Change from Baseline	n	88	83
		Mean	5.60	3.74
		SD	11.867	12.121
		Median	0.00	0.00
		Min.	-23.8	-15.9
		Max.	33.8	39.8

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Vitality (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	30.33	32.90
		SD	28.169	27.839
		Median	25.00	25.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	90
		Mean	49.26	58.06
		SD	30.914	28.744
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	88	83
		Mean	23.01	25.90
		SD	31.308	37.336
		Median	25.00	25.00
		Min.	-50.0	-100.0
		Max.	75.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Vitality (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	41.33	42.34
		SD	11.085	10.955
		Median	39.23	39.23
		Min.	29.4	29.4
		Max.	68.7	68.7
Day 29	SF-12 Score	n	101	90
		Mean	48.77	52.24
		SD	12.164	11.310
		Median	49.07	49.07
		Min.	29.4	29.4
		Max.	68.7	68.7
	Change from Baseline	n	88	83
		Mean	9.05	10.19
		SD	12.320	14.691
		Median	9.84	9.84
		Min.	-19.7	-39.3
		Max.	29.5	39.3

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Social Functioning (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	45.17	48.35
		SD	39.042	37.786
		Median	37.50	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	90
		Mean	79.21	86.67
		SD	29.383	24.055
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	88	83
		Mean	33.52	34.64
		SD	43.695	40.543
		Median	25.00	25.00
		Min.	-75.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Social Functioning (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	37.39	38.52
		SD	13.891	13.444
		Median	34.67	39.11
		Min.	21.3	21.3
		Max.	56.9	56.9
Day 29	SF-12 Score	n	101	90
		Mean	49.50	52.16
		SD	10.453	8.558
		Median	56.90	56.90
		Min.	21.3	21.3
		Max.	56.9	56.9
	Change from Baseline	n	88	83
		Mean	11.93	12.32
		SD	15.546	14.425
		Median	8.90	8.89
		Min.	-26.7	-17.8
		Max.	35.6	35.6

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Emotional (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	68.42	70.31
		SD	28.442	30.465
		Median	75.00	75.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	90
		Mean	83.17	87.78
		SD	23.877	21.527
		Median	100.00	100.00
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	88	83
		Mean	14.91	13.86
		SD	30.786	27.746
		Median	12.50	0.00
		Min.	-75.0	-50.0
		Max.	100.0	100.0

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Emotional (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	43.15	43.94
		SD	11.827	12.668
		Median	45.89	45.89
		Min.	14.7	14.7
		Max.	56.3	56.3
Day 29	SF-12 Score	n	101	90
		Mean	49.28	51.20
		SD	9.928	8.951
		Median	56.28	56.28
		Min.	14.7	14.7
		Max.	56.3	56.3
	Change from Baseline	n	88	83
		Mean	6.20	5.76
		SD	12.801	11.538
		Median	5.19	0.00
		Min.	-31.2	-20.8
		Max.	41.6	41.6

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Mental Health (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	59.92	62.41
		SD	22.636	23.199
		Median	62.50	62.50
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	90
		Mean	71.41	78.89
		SD	21.530	19.260
		Median	75.00	87.50
		Min.	25.0	37.5
		Max.	100.0	100.0
	Change from Baseline	n	88	83
		Mean	12.36	14.16
		SD	23.709	27.175
		Median	12.50	12.50
		Min.	-37.5	-50.0
		Max.	87.5	87.5

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Mental Health (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	45.81	46.96
		SD	10.387	10.646
		Median	47.00	47.00
		Min.	18.3	18.3
		Max.	64.2	64.2
Day 29	SF-12 Score	n	101	90
		Mean	51.09	54.52
		SD	9.881	8.839
		Median	52.74	58.47
		Min.	29.8	35.5
		Max.	64.2	64.2
	Change from Baseline	n	88	83
		Mean	5.67	6.50
		SD	10.880	12.471
		Median	5.74	5.73
		Min.	-17.2	-23.0
		Max.	40.1	40.1

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Physical Component Summary

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	43.67	43.54
		SD	9.321	8.929
		Median	43.71	43.90
		Min.	17.4	20.2
		Max.	62.6	62.1
Day 29	SF-12 Score	n	101	90
		Mean	50.77	49.58
		SD	7.745	8.197
		Median	52.17	51.11
		Min.	22.7	23.5
		Max.	63.8	61.7
	Change from Baseline	n	88	83
		Mean	5.97	5.47
		SD	9.157	8.966
		Median	5.02	3.61
		Min.	-13.3	-11.7
		Max.	31.7	32.2

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Mental Component Summary

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	42.62	44.05
		SD	10.377	10.318
		Median	42.89	43.87
		Min.	13.8	14.5
		Max.	70.0	69.3
Day 29	SF-12 Score	n	101	90
		Mean	49.68	53.78
		SD	9.952	8.573
		Median	52.27	56.26
		Min.	18.3	32.4
		Max.	64.6	65.9
	Change from Baseline	n	88	83
		Mean	8.14	8.69
		SD	11.533	10.881
		Median	6.88	7.12
		Min.	-18.4	-20.6
		Max.	42.9	36.8

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Health Utility Index

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	0.645	0.650
		SD	0.1292	0.1250
		Median	0.621	0.642
		Min.	0.41	0.35
		Max.	1.00	1.00
Day 29	SF-12 Score	n	101	90
		Mean	0.774	0.813
		SD	0.1418	0.1364
		Median	0.782	0.831
		Min.	0.42	0.49
		Max.	1.00	1.00
	Change from Baseline	n	88	83
		Mean	0.131	0.154
		SD	0.1553	0.1507
		Median	0.120	0.140
		Min.	-0.26	-0.14
		Max.	0.45	0.48

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Physical Enhanced (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	48.50	49.72
		SD	26.964	28.381
		Median	50.00	50.00
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	90
		Mean	77.10	79.17
		SD	25.438	22.969
		Median	87.50	87.50
		Min.	0.0	12.5
		Max.	100.0	100.0
	Change from Baseline	n	88	83
		Mean	28.41	28.09
		SD	29.573	30.202
		Median	25.00	25.00
		Min.	-56.3	-25.0
		Max.	87.5	87.5

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Physical Enhanced (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	38.65	39.09
		SD	9.687	10.197
		Median	39.19	39.19
		Min.	21.2	21.2
		Max.	57.2	57.2
Day 29	SF-12 Score	n	101	90
		Mean	48.93	49.67
		SD	9.140	8.253
		Median	52.66	52.66
		Min.	21.2	25.7
		Max.	57.2	57.2
	Change from Baseline	n	88	83
		Mean	10.21	10.09
		SD	10.625	10.851
		Median	8.99	8.99
		Min.	-20.2	-9.0
		Max.	31.4	31.4

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Vitality Enhanced (0-100 score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	36.50	38.01
		SD	24.980	24.272
		Median	34.38	40.63
		Min.	0.0	0.0
		Max.	100.0	100.0
Day 29	SF-12 Score	n	101	90
		Mean	59.03	65.49
		SD	26.138	22.057
		Median	56.25	68.75
		Min.	0.0	0.0
		Max.	100.0	100.0
	Change from Baseline	n	88	83
		Mean	25.14	28.09
		SD	24.565	27.803
		Median	25.00	25.00
		Min.	-50.0	-37.5
		Max.	81.3	93.8

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.6
Summary of Absolute and Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Vitality Enhanced (norm-based score)

Visit			Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Baseline	SF-12 Score	n	150	136
		Mean	40.24	40.96
		SD	11.875	11.538
		Median	39.23	42.21
		Min.	22.9	22.9
		Max.	70.4	70.4
Day 29	SF-12 Score	n	101	90
		Mean	50.95	54.02
		SD	12.423	10.483
		Median	49.63	55.57
		Min.	22.9	22.9
		Max.	70.4	70.4
	Change from Baseline	n	88	83
		Mean	11.95	13.35
		SD	11.676	13.216
		Median	11.89	11.88
		Min.	-23.8	-17.8
		Max.	38.6	44.6

Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
n	36	35
LS Mean (SE)	82.21 (4.496)	84.58 (4.556)
95% C.I.	(73.38, 91.05)	(75.62, 93.53)
LS Mean Change from Baseline (SE)	23.42 (4.496)	25.78 (4.556)
95% C.I.	(14.58, 32.26)	(16.83, 34.74)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		2.36 (6.395)
95% C.I.		(-10.21, 14.93)
p-value		0.713
Corrected Hedge’s g (SE) [1]		0.09 (0.237)
95% C.I.		(-0.38, 0.55)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Physical (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	36	35
LS Mean (SE)	71.45 (4.129)	83.56 (4.186)
95% C.I.	(63.33, 79.56)	(75.33, 91.79)
LS Mean Change from Baseline (SE)	20.26 (4.129)	32.37 (4.186)
95% C.I.	(12.14, 28.37)	(24.14, 40.59)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		12.11 (5.882)
95% C.I.		(0.55, 23.67)
p-value		0.041
Corrected Hedge’s g (SE) [1]		0.48 (0.241)
95% C.I.		(0.01, 0.96)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	36	35
LS Mean (SE)	83.15 (3.503)	80.04 (3.554)
95% C.I.	(76.27, 90.04)	(73.06, 87.03)
LS Mean Change from Baseline (SE)	20.99 (3.503)	17.88 (3.554)
95% C.I.	(14.10, 27.87)	(10.89, 24.86)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-3.11 (4.989)
95% C.I.		(-12.92, 6.69)
p-value		0.534
Corrected Hedge’s g (SE) [1]		-0.15 (0.238)
95% C.I.		(-0.61, 0.32)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: General Health (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	36	35
LS Mean (SE)	67.33 (3.369)	73.16 (3.417)
95% C.I.	(60.71, 73.96)	(66.44, 79.87)
LS Mean Change from Baseline (SE)	12.09 (3.369)	17.91 (3.417)
95% C.I.	(5.47, 18.71)	(11.20, 24.63)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		5.82 (4.799)
95% C.I.		(-3.61, 15.25)
p-value		0.226
Corrected Hedge’s g (SE) [1]		0.28 (0.239)
95% C.I.		(-0.18, 0.75)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Vitality (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	36	35
LS Mean (SE)	60.60 (5.114)	56.06 (5.216)
95% C.I.	(50.55, 70.65)	(45.81, 66.32)
LS Mean Change from Baseline (SE)	24.90 (5.114)	20.36 (5.216)
95% C.I.	(14.85, 34.95)	(10.11, 30.62)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-4.53 (7.253)
95% C.I.		(-18.79, 9.72)
p-value		0.533
Corrected Hedge’s g (SE) [1]		-0.15 (0.238)
95% C.I.		(-0.61, 0.32)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	36	35
LS Mean (SE)	81.32 (4.247)	86.40 (4.307)
95% C.I.	(72.97, 89.66)	(77.94, 94.87)
LS Mean Change from Baseline (SE)	32.93 (4.247)	38.01 (4.307)
95% C.I.	(24.58, 41.27)	(29.55, 46.48)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		5.09 (6.048)
95% C.I.		(-6.80, 16.97)
p-value		0.401
Corrected Hedge’s g (SE) [1]		0.20 (0.238)
95% C.I.		(-0.27, 0.66)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	36	35
LS Mean (SE)	79.99 (3.675)	87.59 (3.720)
95% C.I.	(72.77, 87.21)	(80.28, 94.90)
LS Mean Change from Baseline (SE)	14.00 (3.675)	21.60 (3.720)
95% C.I.	(6.78, 21.22)	(14.29, 28.91)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		7.60 (5.220)
95% C.I.		(-2.66, 17.86)
p-value		0.146
Corrected Hedge’s g (SE) [1]		0.34 (0.239)
95% C.I.		(-0.13, 0.81)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Mental Health (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	36	35
LS Mean (SE)	73.96 (3.502)	74.18 (3.553)
95% C.I.	(67.08, 80.85)	(67.19, 81.16)
LS Mean Change from Baseline (SE)	15.81 (3.502)	16.03 (3.553)
95% C.I.	(8.93, 22.70)	(9.05, 23.01)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.22 (4.982)
95% C.I.		(-9.58, 10.01)
p-value		0.966
Corrected Hedge’s g (SE) [1]		0.01 (0.237)
95% C.I.		(-0.46, 0.48)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Physical Component Summary

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	36	35
LS Mean (SE)	50.52 (1.185)	51.78 (1.202)
95% C.I.	(48.19, 52.85)	(49.42, 54.15)
LS Mean Change from Baseline (SE)	6.62 (1.185)	7.88 (1.202)
95% C.I.	(4.29, 8.95)	(5.52, 10.24)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.26 (1.688)
95% C.I.		(-2.06, 4.58)
p-value		0.457
Corrected Hedge’s g (SE) [1]		0.18 (0.238)
95% C.I.		(-0.29, 0.64)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Mental Component Summary

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	36	35
LS Mean (SE)	50.87 (1.533)	51.75 (1.554)
95% C.I.	(47.86, 53.88)	(48.70, 54.81)
LS Mean Change from Baseline (SE)	8.21 (1.533)	9.10 (1.554)
95% C.I.	(5.20, 11.23)	(6.04, 12.15)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.89 (2.183)
95% C.I.		(-3.41, 5.18)
p-value		0.686
Corrected Hedge’s g (SE) [1]		0.10 (0.238)
95% C.I.		(-0.37, 0.56)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Health Utility Index

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	36	35
LS Mean (SE)	0.78 (0.024)	0.80 (0.024)
95% C.I.	(0.74, 0.83)	(0.75, 0.85)
LS Mean Change from Baseline (SE)	0.14 (0.024)	0.16 (0.024)
95% C.I.	(0.09, 0.19)	(0.11, 0.20)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.02 (0.034)
95% C.I.		(-0.05, 0.08)
p-value		0.623
Corrected Hedge’s g (SE) [1]		0.12 (0.238)
95% C.I.		(-0.35, 0.58)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	36	35
LS Mean (SE)	74.38 (3.801)	84.41 (3.855)
95% C.I.	(66.91, 81.85)	(76.83, 91.98)
LS Mean Change from Baseline (SE)	25.13 (3.801)	35.16 (3.855)
95% C.I.	(17.66, 32.60)	(27.58, 42.73)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		10.03 (5.414)
95% C.I.		(-0.61, 20.67)
p-value		0.065
Corrected Hedge’s g (SE) [1]		0.43 (0.240)
95% C.I.		(-0.04, 0.91)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	36	35
LS Mean (SE)	66.47 (3.862)	67.67 (3.910)
95% C.I.	(58.88, 74.06)	(59.99, 75.36)
LS Mean Change from Baseline (SE)	26.55 (3.862)	27.75 (3.910)
95% C.I.	(18.95, 34.14)	(20.06, 35.43)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.20 (5.480)
95% C.I.		(-9.57, 11.97)
p-value		0.827
Corrected Hedge’s g (SE) [1]		0.05 (0.237)
95% C.I.		(-0.41, 0.52)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
n	41	32
LS Mean (SE)	81.20 (4.208)	85.97 (4.785)
95% C.I.	(72.93, 89.47)	(76.57, 95.37)
LS Mean Change from Baseline (SE)	22.41 (4.208)	27.18 (4.785)
95% C.I.	(14.14, 30.68)	(17.77, 36.58)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		4.77 (6.364)
95% C.I.		(-7.74, 17.28)
p-value		0.455
Corrected Hedge’s g (SE) [1]		0.17 (0.236)
95% C.I.		(-0.29, 0.64)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Physical (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	41	32
LS Mean (SE)	76.47 (3.867)	79.86 (4.401)
95% C.I.	(68.87, 84.07)	(71.21, 88.51)
LS Mean Change from Baseline (SE)	25.28 (3.867)	28.67 (4.401)
95% C.I.	(17.68, 32.88)	(20.02, 37.32)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		3.39 (5.851)
95% C.I.		(-8.11, 14.89)
p-value		0.563
Corrected Hedge’s g (SE) [1]		0.14 (0.236)
95% C.I.		(-0.33, 0.60)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	41	32
LS Mean (SE)	81.70 (3.282)	95.36 (3.736)
95% C.I.	(75.25, 88.15)	(88.02, 102.71)
LS Mean Change from Baseline (SE)	19.53 (3.282)	33.20 (3.736)
95% C.I.	(13.08, 25.99)	(25.86, 40.54)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		13.66 (4.973)
95% C.I.		(3.89, 23.44)
p-value		0.007
Corrected Hedge’s g (SE) [1]		0.64 (0.242)
95% C.I.		(0.17, 1.12)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: General Health (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	41	32
LS Mean (SE)	70.54 (3.157)	68.97 (3.578)
95% C.I.	(64.33, 76.74)	(61.94, 76.00)
LS Mean Change from Baseline (SE)	15.30 (3.157)	13.73 (3.578)
95% C.I.	(9.09, 21.50)	(6.69, 20.76)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.57 (4.773)
95% C.I.		(-10.95, 7.81)
p-value		0.743
Corrected Hedge’s g (SE) [1]		-0.08 (0.236)
95% C.I.		(-0.54, 0.39)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Vitality (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	41	32
LS Mean (SE)	68.92 (4.791)	79.68 (5.406)
95% C.I.	(59.50, 78.33)	(69.05, 90.30)
LS Mean Change from Baseline (SE)	33.22 (4.791)	43.98 (5.406)
95% C.I.	(23.80, 42.63)	(33.35, 54.61)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		10.76 (7.205)
95% C.I.		(-3.40, 24.92)
p-value		0.136
Corrected Hedge’s g (SE) [1]		0.35 (0.238)
95% C.I.		(-0.12, 0.81)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	41	32
LS Mean (SE)	77.12 (3.980)	84.81 (4.514)
95% C.I.	(69.30, 84.94)	(75.94, 93.68)
LS Mean Change from Baseline (SE)	28.73 (3.980)	36.42 (4.514)
95% C.I.	(20.91, 36.55)	(27.55, 45.29)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		7.69 (6.014)
95% C.I.		(-4.13, 19.51)
p-value		0.202
Corrected Hedge’s g (SE) [1]		0.30 (0.237)
95% C.I.		(-0.17, 0.76)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	41	32
LS Mean (SE)	82.69 (3.445)	85.13 (3.938)
95% C.I.	(75.92, 89.46)	(77.39, 92.87)
LS Mean Change from Baseline (SE)	16.70 (3.445)	19.15 (3.938)
95% C.I.	(9.93, 23.47)	(11.41, 26.88)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		2.44 (5.198)
95% C.I.		(-7.77, 12.66)
p-value		0.639
Corrected Hedge’s g (SE) [1]		0.11 (0.236)
95% C.I.		(-0.35, 0.57)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Mental Health (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	41	32
LS Mean (SE)	79.72 (3.282)	81.24 (3.724)
95% C.I.	(73.27, 86.17)	(73.92, 88.56)
LS Mean Change from Baseline (SE)	21.57 (3.282)	23.09 (3.724)
95% C.I.	(15.12, 28.02)	(15.77, 30.41)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.52 (4.954)
95% C.I.		(-8.21, 11.26)
p-value		0.759
Corrected Hedge’s g (SE) [1]		0.07 (0.236)
95% C.I.		(-0.39, 0.53)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Physical Component Summary

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	41	32
LS Mean (SE)	50.38 (1.111)	52.85 (1.261)
95% C.I.	(48.20, 52.56)	(50.37, 55.33)
LS Mean Change from Baseline (SE)	6.48 (1.111)	8.95 (1.261)
95% C.I.	(4.30, 8.66)	(6.47, 11.43)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		2.47 (1.682)
95% C.I.		(-0.83, 5.78)
p-value		0.143
Corrected Hedge’s g (SE) [1]		0.34 (0.238)
95% C.I.		(-0.12, 0.81)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Mental Component Summary

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	41	32
LS Mean (SE)	52.91 (1.437)	54.55 (1.631)
95% C.I.	(50.09, 55.74)	(51.35, 57.76)
LS Mean Change from Baseline (SE)	10.26 (1.437)	11.90 (1.631)
95% C.I.	(7.43, 13.08)	(8.69, 15.10)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.64 (2.171)
95% C.I.		(-2.63, 5.91)
p-value		0.451
Corrected Hedge’s g (SE) [1]		0.18 (0.236)
95% C.I.		(-0.29, 0.64)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Health Utility Index

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	41	32
LS Mean (SE)	0.79 (0.023)	0.87 (0.026)
95% C.I.	(0.75, 0.84)	(0.82, 0.93)
LS Mean Change from Baseline (SE)	0.15 (0.023)	0.23 (0.026)
95% C.I.	(0.10, 0.19)	(0.18, 0.28)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.08 (0.034)
95% C.I.		(0.02, 0.15)
p-value		0.016
Corrected Hedge’s g (SE) [1]		0.57 (0.241)
95% C.I.		(0.10, 1.04)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	41	32
LS Mean (SE)	77.18 (3.561)	82.26 (4.056)
95% C.I.	(70.18, 84.18)	(74.29, 90.23)
LS Mean Change from Baseline (SE)	27.92 (3.561)	33.01 (4.056)
95% C.I.	(20.93, 34.92)	(25.04, 40.98)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		5.09 (5.397)
95% C.I.		(-5.52, 15.69)
p-value		0.347
Corrected Hedge’s g (SE) [1]		0.22 (0.237)
95% C.I.		(-0.24, 0.68)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	41	32
LS Mean (SE)	73.52 (3.615)	79.80 (4.082)
95% C.I.	(66.41, 80.62)	(71.78, 87.82)
LS Mean Change from Baseline (SE)	33.59 (3.615)	39.88 (4.082)
95% C.I.	(26.48, 40.70)	(31.85, 47.90)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		6.29 (5.447)
95% C.I.		(-4.42, 16.99)
p-value		0.250
Corrected Hedge’s g (SE) [1]		0.27 (0.237)
95% C.I.		(-0.20, 0.73)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
n	34	32
LS Mean (SE)	83.04 (4.621)	87.65 (4.768)
95% C.I.	(73.95, 92.12)	(78.27, 97.02)
LS Mean Change from Baseline (SE)	24.24 (4.621)	28.85 (4.768)
95% C.I.	(15.16, 33.32)	(19.48, 38.22)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		4.61 (6.645)
95% C.I.		(-8.45, 17.67)
p-value		0.489
Corrected Hedge’s g (SE) [1]		0.17 (0.247)
95% C.I.		(-0.31, 0.65)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Physical (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	34	32
LS Mean (SE)	80.34 (4.245)	86.54 (4.376)
95% C.I.	(72.00, 88.69)	(77.94, 95.14)
LS Mean Change from Baseline (SE)	29.15 (4.245)	35.35 (4.376)
95% C.I.	(20.81, 37.49)	(26.75, 43.95)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		6.20 (6.097)
95% C.I.		(-5.79, 18.18)
p-value		0.310
Corrected Hedge’s g (SE) [1]		0.25 (0.247)
95% C.I.		(-0.24, 0.73)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	34	31
LS Mean (SE)	85.77 (3.608)	92.63 (3.776)
95% C.I.	(78.68, 92.86)	(85.21, 100.05)
LS Mean Change from Baseline (SE)	23.60 (3.608)	30.46 (3.776)
95% C.I.	(16.51, 30.69)	(23.04, 37.88)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		6.86 (5.226)
95% C.I.		(-3.41, 17.13)
p-value		0.190
Corrected Hedge’s g (SE) [1]		0.32 (0.250)
95% C.I.		(-0.17, 0.81)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: General Health (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	34	32
LS Mean (SE)	72.76 (3.467)	64.43 (3.581)
95% C.I.	(65.95, 79.58)	(57.39, 71.46)
LS Mean Change from Baseline (SE)	17.52 (3.467)	9.18 (3.581)
95% C.I.	(10.70, 24.33)	(2.14, 16.22)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-8.34 (4.986)
95% C.I.		(-18.14, 1.46)
p-value		0.096
Corrected Hedge’s g (SE) [1]		-0.41 (0.249)
95% C.I.		(-0.89, 0.08)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Vitality (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	34	32
LS Mean (SE)	63.88 (5.237)	69.19 (5.403)
95% C.I.	(53.59, 74.17)	(58.57, 79.81)
LS Mean Change from Baseline (SE)	28.18 (5.237)	33.49 (5.403)
95% C.I.	(17.89, 38.47)	(22.88, 44.11)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		5.31 (7.525)
95% C.I.		(-9.48, 20.10)
p-value		0.481
Corrected Hedge’s g (SE) [1]		0.17 (0.247)
95% C.I.		(-0.31, 0.66)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	34	32
LS Mean (SE)	84.22 (4.370)	85.15 (4.508)
95% C.I.	(75.64, 92.81)	(76.29, 94.01)
LS Mean Change from Baseline (SE)	35.83 (4.370)	36.76 (4.508)
95% C.I.	(27.24, 44.42)	(27.90, 45.62)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.93 (6.276)
95% C.I.		(-11.41, 13.26)
p-value		0.883
Corrected Hedge’s g (SE) [1]		0.04 (0.246)
95% C.I.		(-0.45, 0.52)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	34	32
LS Mean (SE)	87.39 (3.773)	90.15 (3.890)
95% C.I.	(79.98, 94.81)	(82.51, 97.80)
LS Mean Change from Baseline (SE)	21.41 (3.773)	24.16 (3.890)
95% C.I.	(13.99, 28.82)	(16.52, 31.81)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		2.76 (5.415)
95% C.I.		(-7.89, 13.40)
p-value		0.612
Corrected Hedge’s g (SE) [1]		0.12 (0.247)
95% C.I.		(-0.36, 0.61)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Mental Health (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	34	32
LS Mean (SE)	77.51 (3.600)	82.08 (3.719)
95% C.I.	(70.43, 84.58)	(74.77, 89.39)
LS Mean Change from Baseline (SE)	19.36 (3.600)	23.93 (3.719)
95% C.I.	(12.29, 26.43)	(16.62, 31.24)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		4.57 (5.176)
95% C.I.		(-5.60, 14.75)
p-value		0.378
Corrected Hedge’s g (SE) [1]		0.22 (0.247)
95% C.I.		(-0.27, 0.70)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Physical Component Summary

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	34	32
LS Mean (SE)	51.48 (1.221)	52.45 (1.258)
95% C.I.	(49.08, 53.88)	(49.98, 54.93)
LS Mean Change from Baseline (SE)	7.58 (1.221)	8.55 (1.258)
95% C.I.	(5.18, 9.98)	(6.08, 11.03)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.98 (1.755)
95% C.I.		(-2.47, 4.42)
p-value		0.579
Corrected Hedge’s g (SE) [1]		0.14 (0.247)
95% C.I.		(-0.35, 0.62)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Mental Component Summary

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	34	32
LS Mean (SE)	52.93 (1.578)	54.24 (1.627)
95% C.I.	(49.83, 56.04)	(51.04, 57.44)
LS Mean Change from Baseline (SE)	10.28 (1.578)	11.59 (1.627)
95% C.I.	(7.18, 13.38)	(8.39, 14.78)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.31 (2.265)
95% C.I.		(-3.14, 5.76)
p-value		0.565
Corrected Hedge’s g (SE) [1]		0.14 (0.247)
95% C.I.		(-0.34, 0.62)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Health Utility Index

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	34	31
LS Mean (SE)	0.83 (0.025)	0.86 (0.026)
95% C.I.	(0.78, 0.88)	(0.81, 0.92)
LS Mean Change from Baseline (SE)	0.19 (0.025)	0.22 (0.026)
95% C.I.	(0.14, 0.24)	(0.17, 0.27)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.03 (0.036)
95% C.I.		(-0.04, 0.10)
p-value		0.381
Corrected Hedge’s g (SE) [1]		0.22 (0.249)
95% C.I.		(-0.27, 0.70)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	34	32
LS Mean (SE)	82.30 (3.911)	86.73 (4.032)
95% C.I.	(74.61, 89.99)	(78.81, 94.65)
LS Mean Change from Baseline (SE)	33.05 (3.911)	37.48 (4.032)
95% C.I.	(25.36, 40.74)	(29.56, 45.40)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		4.43 (5.617)
95% C.I.		(-6.61, 15.47)
p-value		0.431
Corrected Hedge’s g (SE) [1]		0.19 (0.247)
95% C.I.		(-0.29, 0.68)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	34	32
LS Mean (SE)	70.63 (3.960)	76.65 (4.084)
95% C.I.	(62.84, 78.41)	(68.63, 84.68)
LS Mean Change from Baseline (SE)	30.70 (3.960)	36.73 (4.084)
95% C.I.	(22.92, 38.48)	(28.70, 44.76)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		6.03 (5.691)
95% C.I.		(-5.16, 17.21)
p-value		0.290
Corrected Hedge’s g (SE) [1]		0.26 (0.247)
95% C.I.		(-0.23, 0.74)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	62	77
n	26	44
LS Mean (SE)	84.45 (5.284)	81.97 (4.063)
95% C.I.	(74.07, 94.84)	(73.99, 89.96)
LS Mean Change from Baseline (SE)	25.66 (5.284)	23.18 (4.063)
95% C.I.	(15.28, 36.05)	(15.19, 31.17)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-2.48 (6.668)
95% C.I.		(-15.59, 10.62)
p-value		0.710
Corrected Hedge’s g (SE) [1]		-0.09 (0.247)
95% C.I.		(-0.58, 0.39)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Physical (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	26	44
LS Mean (SE)	81.79 (4.855)	79.09 (3.734)
95% C.I.	(72.25, 91.33)	(71.75, 86.43)
LS Mean Change from Baseline (SE)	30.60 (4.855)	27.90 (3.734)
95% C.I.	(21.06, 40.14)	(20.56, 35.24)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-2.70 (6.125)
95% C.I.		(-14.74, 9.33)
p-value		0.660
Corrected Hedge’s g (SE) [1]		-0.11 (0.248)
95% C.I.		(-0.59, 0.38)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	26	44
LS Mean (SE)	98.56 (4.122)	89.25 (3.168)
95% C.I.	(90.46, 106.67)	(83.03, 95.48)
LS Mean Change from Baseline (SE)	36.40 (4.122)	27.09 (3.168)
95% C.I.	(28.30, 44.50)	(20.86, 33.31)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-9.31 (5.199)
95% C.I.		(-19.53, 0.91)
p-value		0.075
Corrected Hedge’s g (SE) [1]		-0.44 (0.250)
95% C.I.		(-0.93, 0.05)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: General Health (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	26	44
LS Mean (SE)	77.56 (3.970)	68.97 (3.056)
95% C.I.	(69.76, 85.36)	(62.96, 74.97)
LS Mean Change from Baseline (SE)	22.32 (3.970)	13.72 (3.056)
95% C.I.	(14.52, 30.12)	(7.72, 19.73)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-8.59 (5.019)
95% C.I.		(-18.46, 1.27)
p-value		0.088
Corrected Hedge’s g (SE) [1]		-0.42 (0.250)
95% C.I.		(-0.91, 0.07)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Vitality (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	26	44
LS Mean (SE)	55.47 (5.997)	66.61 (4.604)
95% C.I.	(43.68, 67.25)	(57.56, 75.65)
LS Mean Change from Baseline (SE)	19.77 (5.997)	30.91 (4.604)
95% C.I.	(7.98, 31.55)	(21.86, 39.96)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		11.14 (7.559)
95% C.I.		(-3.72, 26.00)
p-value		0.142
Corrected Hedge’s g (SE) [1]		0.36 (0.249)
95% C.I.		(-0.13, 0.85)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	26	44
LS Mean (SE)	86.59 (5.002)	88.57 (3.843)
95% C.I.	(76.76, 96.42)	(81.02, 96.12)
LS Mean Change from Baseline (SE)	38.19 (5.002)	40.18 (3.843)
95% C.I.	(28.36, 48.02)	(32.62, 47.73)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.98 (6.312)
95% C.I.		(-10.42, 14.39)
p-value		0.754
Corrected Hedge’s g (SE) [1]		0.08 (0.247)
95% C.I.		(-0.41, 0.56)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	26	44
LS Mean (SE)	90.48 (4.331)	85.07 (3.326)
95% C.I.	(81.97, 99.00)	(78.53, 91.61)
LS Mean Change from Baseline (SE)	24.49 (4.331)	19.08 (3.326)
95% C.I.	(15.98, 33.01)	(12.55, 25.62)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-5.41 (5.440)
95% C.I.		(-16.11, 5.28)
p-value		0.321
Corrected Hedge’s g (SE) [1]		-0.24 (0.248)
95% C.I.		(-0.73, 0.24)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Mental Health (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	26	44
LS Mean (SE)	76.89 (4.118)	79.96 (3.165)
95% C.I.	(68.80, 84.99)	(73.74, 86.18)
LS Mean Change from Baseline (SE)	18.74 (4.118)	21.81 (3.165)
95% C.I.	(10.65, 26.84)	(15.59, 28.03)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		3.07 (5.192)
95% C.I.		(-7.14, 13.27)
p-value		0.555
Corrected Hedge’s g (SE) [1]		0.14 (0.248)
95% C.I.		(-0.34, 0.63)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Physical Component Summary

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	26	44
LS Mean (SE)	53.64 (1.395)	51.40 (1.072)
95% C.I.	(50.90, 56.38)	(49.29, 53.50)
LS Mean Change from Baseline (SE)	9.74 (1.395)	7.49 (1.072)
95% C.I.	(6.99, 12.48)	(5.39, 9.60)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-2.24 (1.759)
95% C.I.		(-5.70, 1.21)
p-value		0.204
Corrected Hedge’s g (SE) [1]		-0.31 (0.249)
95% C.I.		(-0.80, 0.18)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Mental Component Summary

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	26	44
LS Mean (SE)	52.10 (1.807)	53.80 (1.387)
95% C.I.	(48.55, 55.65)	(51.07, 56.53)
LS Mean Change from Baseline (SE)	9.44 (1.807)	11.14 (1.387)
95% C.I.	(5.89, 13.00)	(8.42, 13.87)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.70 (2.276)
95% C.I.		(-2.77, 6.17)
p-value		0.456
Corrected Hedge’s g (SE) [1]		0.18 (0.248)
95% C.I.		(-0.30, 0.67)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Health Utility Index

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	26	44
LS Mean (SE)	0.82 (0.028)	0.83 (0.022)
95% C.I.	(0.76, 0.87)	(0.79, 0.87)
LS Mean Change from Baseline (SE)	0.17 (0.028)	0.19 (0.022)
95% C.I.	(0.12, 0.23)	(0.14, 0.23)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.01 (0.036)
95% C.I.		(-0.06, 0.08)
p-value		0.713
Corrected Hedge’s g (SE) [1]		0.09 (0.247)
95% C.I.		(-0.39, 0.58)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	26	44
LS Mean (SE)	83.70 (4.473)	81.45 (3.439)
95% C.I.	(74.91, 92.49)	(74.69, 88.21)
LS Mean Change from Baseline (SE)	34.45 (4.473)	32.20 (3.439)
95% C.I.	(25.66, 43.24)	(25.44, 38.96)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-2.25 (5.641)
95% C.I.		(-13.34, 8.83)
p-value		0.690
Corrected Hedge’s g (SE) [1]		-0.10 (0.248)
95% C.I.		(-0.58, 0.39)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	26	44
LS Mean (SE)	70.82 (4.529)	71.73 (3.480)
95% C.I.	(61.92, 79.72)	(64.89, 78.57)
LS Mean Change from Baseline (SE)	30.89 (4.529)	31.80 (3.480)
95% C.I.	(21.99, 39.79)	(24.96, 38.64)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.91 (5.712)
95% C.I.		(-10.32, 12.14)
p-value		0.874
Corrected Hedge’s g (SE) [1]		0.04 (0.247)
95% C.I.		(-0.45, 0.52)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Physical Functioning (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
n	88	83
LS Mean (SE)	75.09 (2.890)	72.73 (2.957)
95% C.I.	(69.41, 80.77)	(66.92, 78.54)
LS Mean Change from Baseline (SE)	16.29 (2.890)	13.94 (2.957)
95% C.I.	(10.61, 21.97)	(8.12, 19.75)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-2.36 (4.129)
95% C.I.		(-10.47, 5.76)
p-value		0.569
Corrected Hedge’s g (SE) [1]		-0.09 (0.153)
95% C.I.		(-0.39, 0.21)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Physical (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	88	83
LS Mean (SE)	77.72 (2.640)	75.19 (2.719)
95% C.I.	(72.53, 82.90)	(69.85, 80.53)
LS Mean Change from Baseline (SE)	26.52 (2.640)	24.00 (2.719)
95% C.I.	(21.34, 31.71)	(18.65, 29.34)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-2.53 (3.788)
95% C.I.		(-9.97, 4.92)
p-value		0.506
Corrected Hedge’s g (SE) [1]		-0.10 (0.153)
95% C.I.		(-0.40, 0.20)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Bodily Pain (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	88	83
LS Mean (SE)	85.65 (2.241)	86.92 (2.310)
95% C.I.	(81.25, 90.06)	(82.38, 91.45)
LS Mean Change from Baseline (SE)	23.48 (2.241)	24.75 (2.310)
95% C.I.	(19.08, 27.89)	(20.21, 29.29)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		1.26 (3.216)
95% C.I.		(-5.06, 7.58)
p-value		0.695
Corrected Hedge’s g (SE) [1]		0.06 (0.153)
95% C.I.		(-0.24, 0.36)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: General Health (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	88	83
LS Mean (SE)	70.98 (2.156)	67.51 (2.222)
95% C.I.	(66.74, 75.21)	(63.15, 71.88)
LS Mean Change from Baseline (SE)	15.73 (2.156)	12.27 (2.222)
95% C.I.	(11.49, 19.97)	(7.90, 16.64)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-3.46 (3.094)
95% C.I.		(-9.54, 2.62)
p-value		0.264
Corrected Hedge’s g (SE) [1]		-0.17 (0.153)
95% C.I.		(-0.47, 0.13)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Vitality (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	88	83
LS Mean (SE)	52.60 (3.285)	58.65 (3.359)
95% C.I.	(46.15, 59.06)	(52.05, 65.25)
LS Mean Change from Baseline (SE)	16.90 (3.285)	22.95 (3.359)
95% C.I.	(10.45, 23.36)	(16.35, 29.55)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		6.05 (4.678)
95% C.I.		(-3.15, 15.24)
p-value		0.197
Corrected Hedge’s g (SE) [1]		0.20 (0.153)
95% C.I.		(-0.10, 0.50)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Social Functioning (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	88	83
LS Mean (SE)	80.13 (2.717)	85.96 (2.799)
95% C.I.	(74.79, 85.47)	(80.46, 91.46)
LS Mean Change from Baseline (SE)	31.73 (2.717)	37.57 (2.799)
95% C.I.	(26.39, 37.07)	(32.07, 43.07)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		5.83 (3.903)
95% C.I.		(-1.84, 13.50)
p-value		0.136
Corrected Hedge’s g (SE) [1]		0.23 (0.154)
95% C.I.		(-0.07, 0.53)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Emotional (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	88	83
LS Mean (SE)	83.28 (2.347)	85.66 (2.431)
95% C.I.	(78.67, 87.89)	(80.88, 90.44)
LS Mean Change from Baseline (SE)	17.29 (2.347)	19.67 (2.431)
95% C.I.	(12.68, 21.90)	(14.90, 24.45)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		2.38 (3.369)
95% C.I.		(-4.24, 9.00)
p-value		0.480
Corrected Hedge’s g (SE) [1]		0.11 (0.153)
95% C.I.		(-0.19, 0.41)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Mental Health (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	88	83
LS Mean (SE)	71.81 (2.239)	77.64 (2.323)
95% C.I.	(67.41, 76.21)	(73.08, 82.21)
LS Mean Change from Baseline (SE)	13.66 (2.239)	19.49 (2.323)
95% C.I.	(9.26, 18.06)	(14.93, 24.06)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		5.83 (3.219)
95% C.I.		(-0.50, 12.16)
p-value		0.071
Corrected Hedge’s g (SE) [1]		0.28 (0.154)
95% C.I.		(-0.03, 0.58)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Physical Component Summary

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	88	83
LS Mean (SE)	50.73 (0.760)	49.29 (0.781)
95% C.I.	(49.24, 52.22)	(47.76, 50.83)
LS Mean Change from Baseline (SE)	6.83 (0.760)	5.39 (0.781)
95% C.I.	(5.34, 8.32)	(3.85, 6.92)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		-1.44 (1.090)
95% C.I.		(-3.58, 0.70)
p-value		0.187
Corrected Hedge’s g (SE) [1]		-0.20 (0.153)
95% C.I.		(-0.50, 0.10)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Mental Component Summary

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	88	83
LS Mean (SE)	50.20 (0.981)	53.22 (1.015)
95% C.I.	(48.27, 52.12)	(51.22, 55.21)
LS Mean Change from Baseline (SE)	7.54 (0.981)	10.56 (1.015)
95% C.I.	(5.61, 9.47)	(8.57, 12.56)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		3.02 (1.414)
95% C.I.		(0.24, 5.80)
p-value		0.034
Corrected Hedge’s g (SE) [1]		0.33 (0.154)
95% C.I.		(0.02, 0.63)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Health Utility Index

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	88	83
LS Mean (SE)	0.78 (0.015)	0.81 (0.016)
95% C.I.	(0.75, 0.81)	(0.78, 0.84)
LS Mean Change from Baseline (SE)	0.13 (0.015)	0.17 (0.016)
95% C.I.	(0.10, 0.16)	(0.13, 0.20)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.03 (0.022)
95% C.I.		(-0.01, 0.07)
p-value		0.162
Corrected Hedge’s g (SE) [1]		0.21 (0.153)
95% C.I.		(-0.09, 0.51)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Role Physical Enhanced (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	88	83
LS Mean (SE)	78.06 (2.431)	78.46 (2.504)
95% C.I.	(73.28, 82.84)	(73.54, 83.38)
LS Mean Change from Baseline (SE)	28.81 (2.431)	29.21 (2.504)
95% C.I.	(24.03, 33.59)	(24.29, 34.13)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		0.40 (3.489)
95% C.I.		(-6.46, 7.26)
p-value		0.909
Corrected Hedge’s g (SE) [1]		0.02 (0.153)
95% C.I.		(-0.28, 0.32)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.7
Analysis of Change from Baseline in SF-12 Hybrid at Day 29 by Week 24 Baseline Viral Load

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Domain: Vitality Enhanced (0-100 score)

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
n	88	83
LS Mean (SE)	61.65 (2.473)	66.34 (2.536)
95% C.I.	(56.79, 66.51)	(61.36, 71.33)
LS Mean Change from Baseline (SE)	21.73 (2.473)	26.42 (2.536)
95% C.I.	(16.87, 26.59)	(21.43, 31.40)
Sotrovimab (500mg IV) vs. Placebo		
Difference (SE)		4.69 (3.534)
95% C.I.		(-2.26, 11.64)
p-value		0.186
Corrected Hedge’s g (SE) [1]		0.20 (0.153)
95% C.I.		(-0.10, 0.50)

[1] Corrected Hedge’s g is derived from the LS means and associated SEs.
Note: Analysis was performed using an ANCOVA model, adjusting for treatment, week 24 baseline viral load category, baseline and treatment by week 24 baseline viral load category interaction.
Note: SF-12 was scheduled for the Expansion phase only.
PPD

Population: Intent-to-Treat

Table 214.8
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Week 24 Baseline Viral Load - GBA Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	20 (21%)	16 (16%)
Non-responder	16 (16%)	19 (19%)
Missing [1]	61 (63%)	66 (65%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.38
95% C.I.		(0.67, 2.85)
p-value		0.385
Inverse Relative Risk [3]		1.30
95% C.I.		(0.72, 2.36)
p-value		0.386
Risk Difference (%) [4]		4.78
95% C.I.		(-5.97, 15.53)
p-value		0.462

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).
PPD

Population: Intent-to-Treat

Table 214.8
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Week 24 Baseline Viral Load - GBA Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	21 (24%)	25 (33%)
Non-responder	20 (23%)	7 (9%)
Missing [1]	46 (53%)	44 (58%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.65
95% C.I.		(0.33, 1.29)
p-value		0.217
Inverse Relative Risk [3]		0.73
95% C.I.		(0.45, 1.20)
p-value		0.218
Risk Difference (%) [4]		-8.76
95% C.I.		(-22.63, 5.12)
p-value		0.228

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).
PPD

Population: Intent-to-Treat

Table 214.8
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Week 24 Baseline Viral Load - GBA Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	15 (26%)	18 (28%)
Non-responder	19 (33%)	14 (22%)
Missing [1]	24 (41%)	32 (50%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.89
95% C.I.		(0.40, 1.99)
p-value		0.779
Inverse Relative Risk [3]		0.92
95% C.I.		(0.51, 1.65)
p-value		0.780
Risk Difference (%) [4]		-2.26
95% C.I.		(-18.02, 13.50)
p-value		0.840

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).
PPD

Population: Intent-to-Treat

Table 214.8
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Week 24 Baseline Viral Load - GBA Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	62	77
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	10 (16%)	20 (26%)
Non-responder	16 (26%)	24 (31%)
Missing [1]	36 (58%)	33 (43%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.55
95% C.I.		(0.23, 1.28)
p-value		0.165
Inverse Relative Risk [3]		0.62
95% C.I.		(0.31, 1.23)
p-value		0.171
Risk Difference (%) [4]		-9.84
95% C.I.		(-23.25, 3.56)
p-value		0.214

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).
PPD

Population: Intent-to-Treat

Table 214.8
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Week 24 Baseline Viral Load - GBA Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
SF-12 Hybrid MCS Responder Status - GBA Approach, n (%)		
Responder	31 (17%)	37 (22%)
Non-responder	57 (30%)	46 (28%)
Missing [1]	99 (53%)	83 (50%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.69
95% C.I.		(0.41, 1.18)
p-value		0.176
Inverse Relative Risk [3]		0.74
95% C.I.		(0.48, 1.14)
p-value		0.177
Risk Difference (%) [4]		-5.71
95% C.I.		(-13.99, 2.56)
p-value		0.180

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).
PPD

Population: Intent-to-Treat

Table 214.9
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Week 24 Baseline Viral Load - GBA Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	16 (16%)	18 (18%)
Non-responder	20 (21%)	17 (17%)
Missing [1]	61 (63%)	66 (65%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.91
95% C.I.		(0.43, 1.91)
p-value		0.805
Inverse Relative Risk [3]		0.93
95% C.I.		(0.50, 1.71)
p-value		0.805
Risk Difference (%) [4]		-1.33
95% C.I.		(-11.83, 9.17)
p-value		0.853

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).
PPD

Population: Intent-to-Treat

Table 214.9
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Week 24 Baseline Viral Load - GBA Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	17 (20%)	22 (29%)
Non-responder	24 (28%)	10 (13%)
Missing [1]	46 (53%)	44 (58%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.60
95% C.I.		(0.29, 1.23)
p-value		0.163
Inverse Relative Risk [3]		0.68
95% C.I.		(0.39, 1.17)
p-value		0.164
Risk Difference (%) [4]		-9.41
95% C.I.		(-22.57, 3.76)
p-value		0.199

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).
PPD

Population: Intent-to-Treat

Table 214.9
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Week 24 Baseline Viral Load - GBA Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	11 (19%)	17 (27%)
Non-responder	23 (40%)	15 (23%)
Missing [1]	24 (41%)	32 (50%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.65
95% C.I.		(0.27, 1.53)
p-value		0.321
Inverse Relative Risk [3]		0.71
95% C.I.		(0.37, 1.40)
p-value		0.325
Risk Difference (%) [4]		-7.60
95% C.I.		(-22.39, 7.20)
p-value		0.391

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).
PPD

Population: Intent-to-Treat

Table 214.9
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Week 24 Baseline Viral Load - GBA Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	62	77
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	12 (19%)	20 (26%)
Non-responder	14 (23%)	24 (31%)
Missing [1]	36 (58%)	33 (43%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.68
95% C.I.		(0.30, 1.54)
p-value		0.359
Inverse Relative Risk [3]		0.75
95% C.I.		(0.40, 1.40)
p-value		0.363
Risk Difference (%) [4]		-6.62
95% C.I.		(-20.50, 7.26)
p-value		0.421

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).
PPD

Population: Intent-to-Treat

Table 214.9
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Week 24 Baseline Viral Load - GBA Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
SF-12 Hybrid PCS Responder Status - GBA Approach, n (%)		
Responder	30 (16%)	27 (16%)
Non-responder	58 (31%)	56 (34%)
Missing [1]	99 (53%)	83 (50%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.98
95% C.I.		(0.56, 1.74)
p-value		0.955
Inverse Relative Risk [3]		0.99
95% C.I.		(0.61, 1.59)
p-value		0.955
Risk Difference (%) [4]		-0.22
95% C.I.		(-7.92, 7.47)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).
PPD

Population: Intent-to-Treat

Table 214.10
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Week 24 Baseline Viral Load - QualityMetric Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	21 (22%)	19 (19%)
Non-responder	15 (15%)	16 (16%)
Missing [1]	61 (63%)	66 (65%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.19
95% C.I.		(0.60, 2.39)
p-value		0.620
Inverse Relative Risk [3]		1.15
95% C.I.		(0.66, 2.00)
p-value		0.620
Risk Difference (%) [4]		2.84
95% C.I.		(-8.35, 14.03)
p-value		0.724

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).
PPD

Population: Intent-to-Treat

Table 214.10
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Week 24 Baseline Viral Load - QualityMetric Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	23 (26%)	25 (33%)
Non-responder	18 (21%)	7 (9%)
Missing [1]	46 (53%)	44 (58%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.73
95% C.I.		(0.37, 1.44)
p-value		0.368
Inverse Relative Risk [3]		0.80
95% C.I.		(0.50, 1.29)
p-value		0.368
Risk Difference (%) [4]		-6.46
95% C.I.		(-20.51, 7.59)
p-value		0.394

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).
PPD

Population: Intent-to-Treat

Table 214.10
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Week 24 Baseline Viral Load - QualityMetric Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	19 (33%)	20 (31%)
Non-responder	15 (26%)	12 (19%)
Missing [1]	24 (41%)	32 (50%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.07
95% C.I.		(0.50, 2.30)
p-value		0.859
Inverse Relative Risk [3]		1.05
95% C.I.		(0.62, 1.76)
p-value		0.859
Risk Difference (%) [4]		1.51
95% C.I.		(-15.07, 18.09)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).
PPD

Population: Intent-to-Treat

Table 214.10
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Week 24 Baseline Viral Load - QualityMetric Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	62	77
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	11 (18%)	23 (30%)
Non-responder	15 (24%)	21 (27%)
Missing [1]	36 (58%)	33 (43%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.51
95% C.I.		(0.22, 1.14)
p-value		0.102
Inverse Relative Risk [3]		0.59
95% C.I.		(0.31, 1.12)
p-value		0.109
Risk Difference (%) [4]		-12.13
95% C.I.		(-26.09, 1.83)
p-value		0.115

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).
PPD

Population: Intent-to-Treat

Table 214.10
Summary and Analysis of Proportion of SF-12 Hybrid MCS Responders at Day 29 by Week 24 Baseline Viral Load - QualityMetric Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
SF-12 Hybrid MCS Responder Status - QualityMetric Approach, n (%)		
Responder	44 (24%)	43 (26%)
Non-responder	44 (24%)	40 (24%)
Missing [1]	99 (53%)	83 (50%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.88
95% C.I.		(0.54, 1.43)
p-value		0.606
Inverse Relative Risk [3]		0.91
95% C.I.		(0.63, 1.31)
p-value		0.606
Risk Difference (%) [4]		-2.37
95% C.I.		(-11.40, 6.65)
p-value		0.623

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).
PPD

Population: Intent-to-Treat

Table 214.11
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Week 24 Baseline Viral Load - QualityMetric Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <2228 copies/mL (<LLQ)
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	97	101
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	19 (20%)	19 (19%)
Non-responder	17 (18%)	16 (16%)
Missing [1]	61 (63%)	66 (65%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		1.05
95% C.I.		(0.52, 2.13)
p-value		0.890
Inverse Relative Risk [3]		1.04
95% C.I.		(0.59, 1.84)
p-value		0.890
Risk Difference (%) [4]		0.78
95% C.I.		(-10.20, 11.75)
p-value		>0.999

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).
PPD

Population: Intent-to-Treat

Table 214.11
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Week 24 Baseline Viral Load - QualityMetric Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): <=log 10^5
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	87	76
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	20 (23%)	22 (29%)
Non-responder	21 (24%)	10 (13%)
Missing [1]	46 (53%)	44 (58%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.73
95% C.I.		(0.36, 1.48)
p-value		0.387
Inverse Relative Risk [3]		0.79
95% C.I.		(0.47, 1.34)
p-value		0.387
Risk Difference (%) [4]		-5.96
95% C.I.		(-19.45, 7.54)
p-value		0.474

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).
PPD

Population: Intent-to-Treat

Table 214.11
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Week 24 Baseline Viral Load - QualityMetric Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^5 - <=log 10^6
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	58	64
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	14 (24%)	20 (31%)
Non-responder	20 (34%)	12 (19%)
Missing [1]	24 (41%)	32 (50%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.70
95% C.I.		(0.31, 1.56)
p-value		0.383
Inverse Relative Risk [3]		0.77
95% C.I.		(0.43, 1.38)
p-value		0.386
Risk Difference (%) [4]		-7.11
95% C.I.		(-22.93, 8.71)
p-value		0.424

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).
PPD

Population: Intent-to-Treat

Table 214.11
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Week 24 Baseline Viral Load - QualityMetric Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^6 - <=log 10^7
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	62	77
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	17 (27%)	27 (35%)
Non-responder	9 (15%)	17 (22%)
Missing [1]	36 (58%)	33 (43%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.70
95% C.I.		(0.34, 1.45)
p-value		0.337
Inverse Relative Risk [3]		0.78
95% C.I.		(0.47, 1.30)
p-value		0.342
Risk Difference (%) [4]		-7.65
95% C.I.		(-23.04, 7.75)
p-value		0.365

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).
PPD

Population: Intent-to-Treat

Table 214.11
Summary and Analysis of Proportion of SF-12 Hybrid PCS Responders at Day 29 by Week 24 Baseline Viral Load - QualityMetric Approach

Week 24 Baseline SARS-CoV-2 viral load (copies/mL): >log 10^7
Visit: Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Number of subjects in subgroup	187	166
SF-12 Hybrid PCS Responder Status - QualityMetric Approach, n (%)		
Responder	38 (20%)	37 (22%)
Non-responder	50 (27%)	46 (28%)
Missing [1]	99 (53%)	83 (50%)
Sotrovimab (500mg IV) vs. Placebo:		
Inverse Odds Ratio [2]		0.89
95% C.I.		(0.53, 1.48)
p-value		0.652
Inverse Relative Risk [3]		0.91
95% C.I.		(0.61, 1.36)
p-value		0.652
Risk Difference (%) [4]		-1.97
95% C.I.		(-10.53, 6.60)
p-value		0.697

[1] Available data were used in the analysis as collected, regardless of the occurrence of intercurrent events. Subjects with missing response status were considered non-responders.
Note: Analysis was performed adjusting for treatment, week 24 baseline viral load category and week 24 baseline viral load category by treatment interaction, using [2] logistic regression, [3] Poisson model.
[4] P-value is calculated using a 2-sided Fisher’s Exact test.
Note: Inverse odds ratio/relative risk <1, risk difference <0 correspond to a benefit of sotrovimab over placebo.
Note: SF-12 was scheduled for the Expansion phase only.
Note: Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).
PPD

Population: Intent-to-Treat

Table 214.12
P-values for Interactions of Treatment with Subgroups for Time to sustained (>=48 hours) Symptom Alleviation using the FLU-PRO Plus Over the First 21 Days

Interaction of Treatment with:	P-value [1]
Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.681

[1] Interaction p-values obtained from Cox proportional hazards models with covariates of treatment, subgroup and subgroup by treatment interaction.

PPD

Population: Intent-to-Treat

Table 214.13
P-values for Interactions of Treatment with Subgroups for Proportion of Subjects Achieving Sustained (>=48hr) Symptom Alleviation using the FLU-PRO Plus at Day 21

Interaction of Treatment with:	P-value [1]
Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.482

[1] Interaction p-values obtained from Poisson models with covariates of treatment, region (North America, Europe, South America), duration of symptoms (<=3, >=4 days), age (<=70, >70 years old), gender (male, female), subgroup (if not already in the model) and subgroup by treatment interaction.

PPD

Protocol: 214367
Population: Intent-to-Treat

Table 214.14
P-values for Interactions of Treatment with Subgroups for Proportion of FLU-PRO Plus Total Score Responders at Day 21

Interaction of Treatment with:	P-value [1]
Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.333

[1] Interaction p-values obtained from Poisson models with covariates of treatment, subgroup and subgroup by treatment interaction.

PPD

Population: Intent-to-Treat

Table 214.15
P-values for Interactions of Treatment with Subgroups for Change from Baseline in Work Productivity and Activity Impairment (WPAI) Scores at Day 29

Interaction of Treatment with:	Domain	P-value [1]
Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	Work time missed due to health (%)	0.013
	Impairment while working due to health (%)	0.095
	Overall work impairment due to health (%)	0.013
	Activity impairment due to health (%)	0.238

[1] Interaction p-values obtained from ANCOVA models with covariates of treatment, baseline, subgroup and subgroup by treatment interaction.
Note: WPAI was scheduled for the Expansion phase only.

PPD

Table 214.16
P-values for Interactions of Treatment with Subgroups for Change from Baseline in SF-12 Hybrid at Day 29

Interaction of Treatment with:	Domain	P-value [1]
Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	Physical Functioning (0-100 score)	0.809
	Role Physical (0-100 score)	0.241
	Bodily Pain (0-100 score)	0.017
	General Health (0-100 score)	0.211
	Vitality (0-100 score)	0.557
	Social Functioning (0-100 score)	0.927
	Role Emotional (0-100 score)	0.552
	Mental Health (0-100 score)	0.885
	Physical Component Summary	0.176
	Mental Component Summary	0.922
	Health Utility Index	0.613
	Role Physical Enhanced (0-100 score)	0.507
	Vitality Enhanced (0-100 score)	0.926

[1] Interaction p-values obtained from ANCOVA models with covariates of treatment, baseline, subgroup and subgroup by treatment interaction.
Note: SF-12 was scheduled for the Expansion phase only.

PPD

Population: Intent-to-Treat

Table 214.17
P-values for Interactions of Treatment with Subgroups for Proportion of SF-12 MCS and PCS Responders at Day 29 - GBA Approach

Domain	Interaction of Treatment with:	P-value [1]
SF-12 Hybrid MCS Responder - GBA	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.484
SF-12 Hybrid PCS Responder - GBA	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.834

[1] Interaction p-values obtained from Poisson models with covariates of treatment, subgroup and subgroup by treatment interaction.
Note: MCS response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 and for PCS a change from baseline >= 8.7 (GBA Approach).

PPD

Population: Intent-to-Treat

Table 214.18
P-values for Interactions of Treatment with Subgroups for Proportion of SF-12 MCS and PCS Responders at Day 29 - QualityMetric Approach

Domain	Interaction of Treatment with:	P-value [1]
SF-12 Hybrid MCS Responder - QualityMetric	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.543
SF-12 Hybrid PCS Responder - QualityMetric	Week 24 Baseline SARS-CoV-2 viral load (<2228 (<LLQ), <=log 10^5, >log 10^5 - <=log 10^6, >log 10^6 - <=log 10^7, >log 10^7 copies/mL)	0.930

[1] Interaction p-values obtained from Poisson models with covariates of treatment, subgroup and subgroup by treatment interaction.
Note: MCS response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 and for PCS a change from baseline >=6 (QualityMetric Approach).
PPD

Protocol: 214367
Population: Intent-to-Treat

Table 24.6
Summary and Analysis of Time to FLU-PRO Plus Total Score Response by Day 29

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Responder [1]	302 (57%)	323 (61%)
Censored	227 (43%)	205 (39%)
75th Percentile (95% C.I.)	11 (10,12)	8 (7,8)
Median (95% C.I.)	6 (5,7)	4 (4,5)
25th Percentile (95% C.I.)	3 (NE,NE)	3 (2,3)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.77
95% C.I.		(0.66, 0.90)
p-value		0.002

[1] Response is defined as a change from baseline in FLU-PRO Plus total score <= -0.6.
Note: Event=Responder. Subjects without the event are censored at the latest of (treatment start date or randomization date if treatment start date is missing, latest non-missing assessment date on or prior to Day 29).
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with a covariate of treatment.
Note: Inverse hazard ratio <1 corresponds to a benefit of Sotrovimab over Placebo.

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Table 24.13
Summary and Analysis of Time to SF-12 Hybrid MCS Response by Day 29 - GBA Approach

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Responder [1]	133 (25%)	158 (30%)
Censored	396 (75%)	370 (70%)
75th Percentile (95% C.I.)	29 (19,29)	29 (16,29)
Median (95% C.I.)	15 (NE,NE)	15 (NE,NE)
25th Percentile (95% C.I.)	15 (NE,NE)	15 (NE,NE)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.96
95% C.I.		(0.75, 1.23)
p-value		0.758

[1] Response is defined as a change from baseline in SF-12 Hybrid MCS score >= 9.9 (GBA Approach).
Note: Event=Responder. Subjects without the event are censored at the latest of (treatment start date or randomization date if treatment start date is missing, latest non-missing assessment date on or prior to Day 29).
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with a covariate of treatment.
Note: Inverse hazard ratio <1 corresponds to a benefit of Sotrovimab over Placebo.

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Table 24.14
Summary and Analysis of Time to SF-12 Hybrid PCS Response by Day 29 - GBA Approach

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Responder [1]	108 (20%)	146 (28%)
Censored	421 (80%)	382 (72%)
75th Percentile (95% C.I.)	29 (NE,NE)	29 (16,29)
Median (95% C.I.)	16 (15,29)	15 (NE,NE)
25th Percentile (95% C.I.)	15 (NE,NE)	15 (NE,NE)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.71
95% C.I.		(0.54, 0.93)
p-value		0.013

[1] Response is defined as a change from baseline in SF-12 Hybrid PCS score >= 8.7 (GBA Approach).
Note: Event=Responder. Subjects without the event are censored at the latest of (treatment start date or randomization date if treatment start date is missing, latest non-missing assessment date on or prior to Day 29).
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with a covariate of treatment.
Note: Inverse hazard ratio <1 corresponds to a benefit of Sotrovimab over Placebo.

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Table 24.15
Summary and Analysis of Time to SF-12 Hybrid MCS Response by Day 29 - QualityMetric Approach

	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Responder [1]	161 (30%)	181 (34%)
Censored	368 (70%)	347 (66%)
75th Percentile (95% C.I.)	29 (28,29)	29 (16,29)
Median (95% C.I.)	15 (NE,NE)	15 (NE,NE)
25th Percentile (95% C.I.)	15 (NE,NE)	15 (NE,NE)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.94
95% C.I.		(0.75, 1.18)
p-value		0.607

[1] Response is defined as a change from baseline in SF-12 Hybrid MCS score >=7 (QualityMetric Approach).
Note: Event=Responder. Subjects without the event are censored at the latest of (treatment start date or randomization date if treatment start date is missing, latest non-missing assessment date on or prior to Day 29).
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with a covariate of treatment.
Note: Inverse hazard ratio <1 corresponds to a benefit of Sotrovimab over Placebo.

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Table 24.16
Summary and Analysis of Time to SF-12 Hybrid PCS Response by Day 29 - QualityMetric Approach

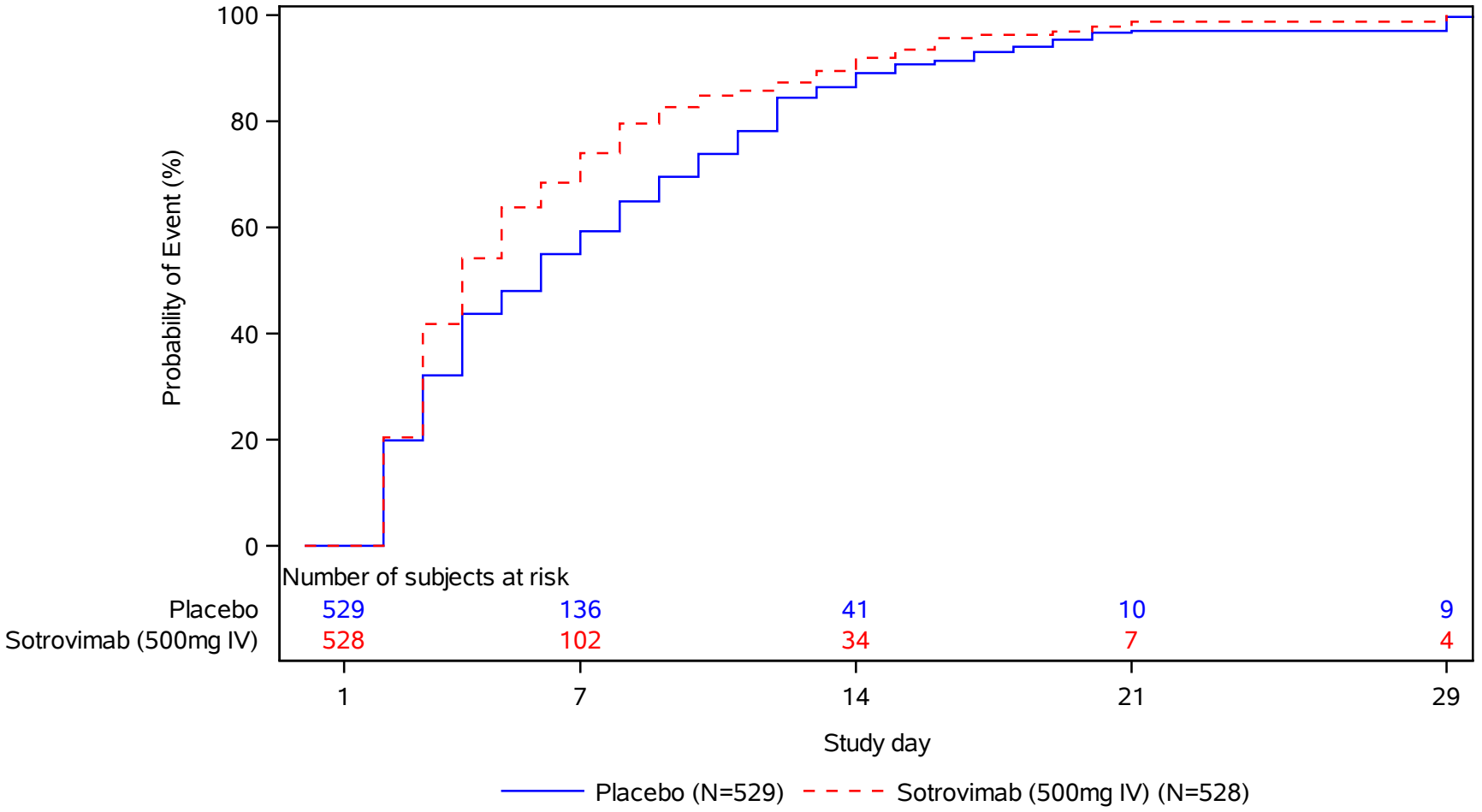
	Placebo (N=529)	Sotrovimab (500mg IV) (N=528)
Responder [1]	143 (27%)	182 (34%)
Censored	386 (73%)	346 (66%)
75th Percentile (95% C.I.)	29 (NE,NE)	29 (16,29)
Median (95% C.I.)	15 (15,16)	15 (NE,NE)
25th Percentile (95% C.I.)	15 (NE,NE)	15 (NE,NE)
Sotrovimab (500mg IV) vs. Placebo		
Inverse Hazard Ratio		0.79
95% C.I.		(0.62, 1.00)
p-value		0.047

[1] Response is defined as a change from baseline in SF-12 Hybrid PCS score >=6 (QualityMetric Approach).
Note: Event=Responder. Subjects without the event are censored at the latest of (treatment start date or randomization date if treatment start date is missing, latest non-missing assessment date on or prior to Day 29).
Note: Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
Note: Inverse hazard ratio and 95% C.I. are from a Cox proportional hazards model with a covariate of treatment. Inverse hazard ratio <1 corresponds to a benefit of Sotrovimab over Placebo.

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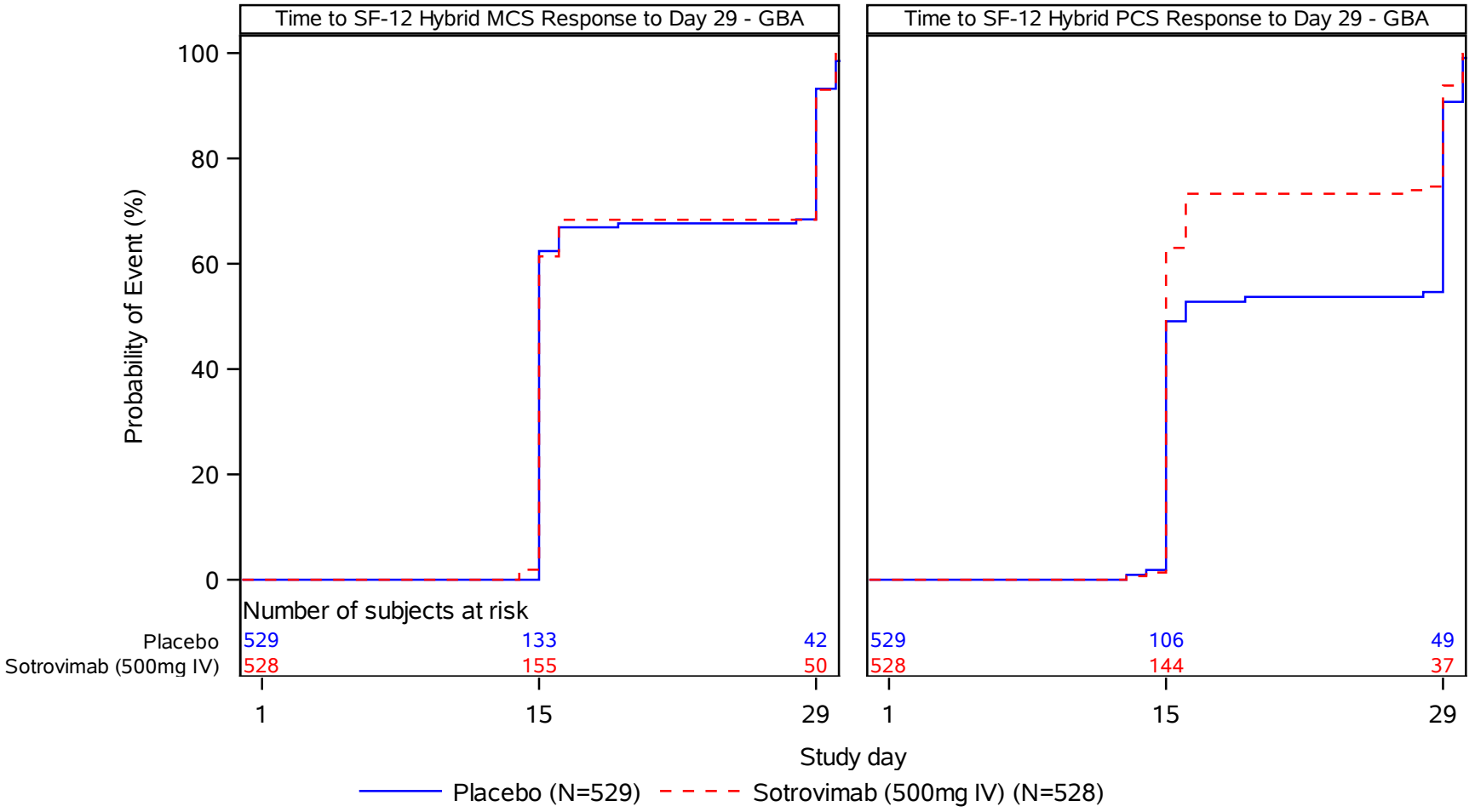
Figure 24.3
Kaplan-Meier Plot of Time to FLU-PRO Plus Total Score Response by Day 29



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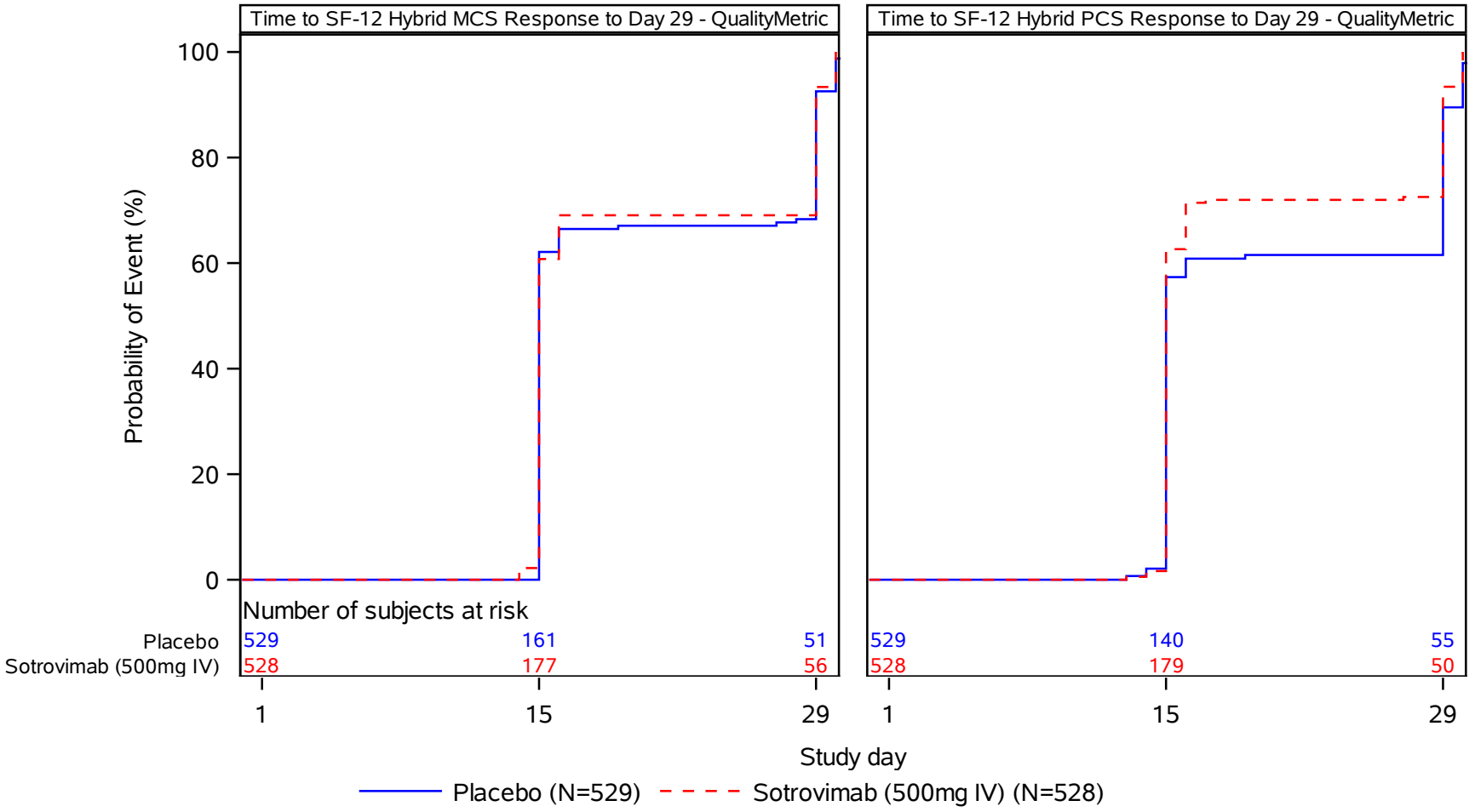
Figure 24.6
Kaplan-Meier Plot of Time to SF-12 Hybrid MCS and PCS Response by Day 29 - GBA Approach



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Figure 24.7
Kaplan-Meier Plot of Time to SF-12 Hybrid MCS and PCS Response by Day 29 - QualityMetric Approach



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