

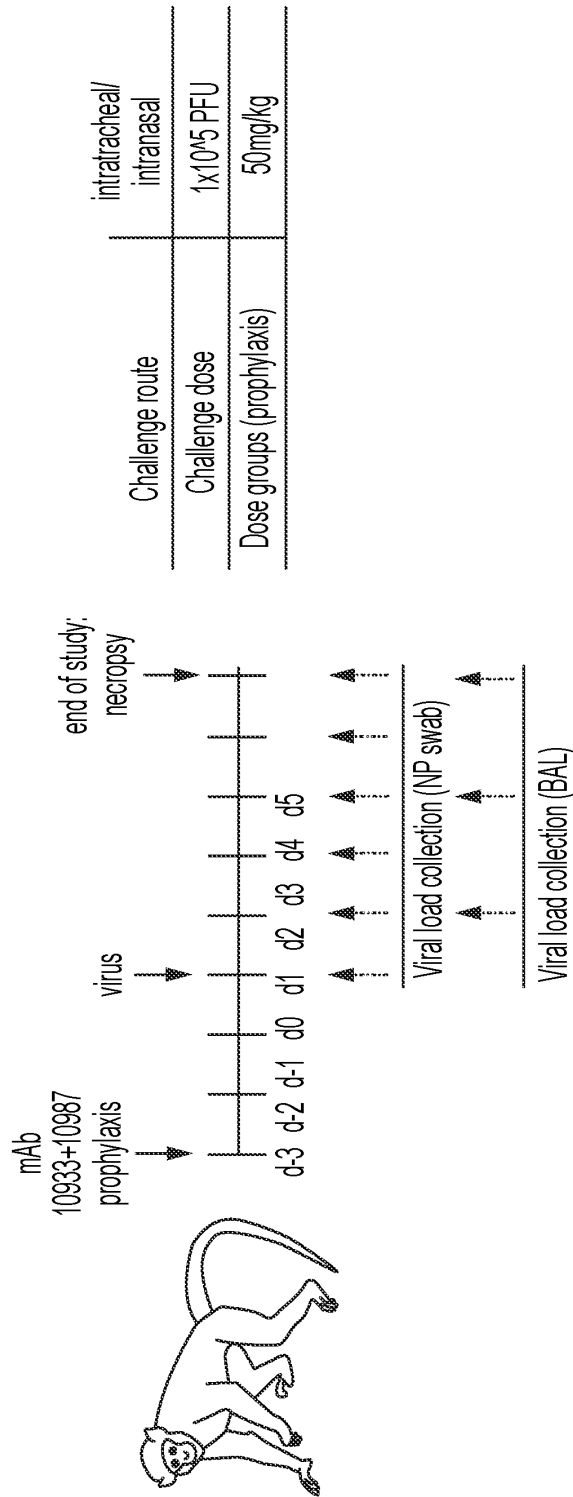


FIG. 1A

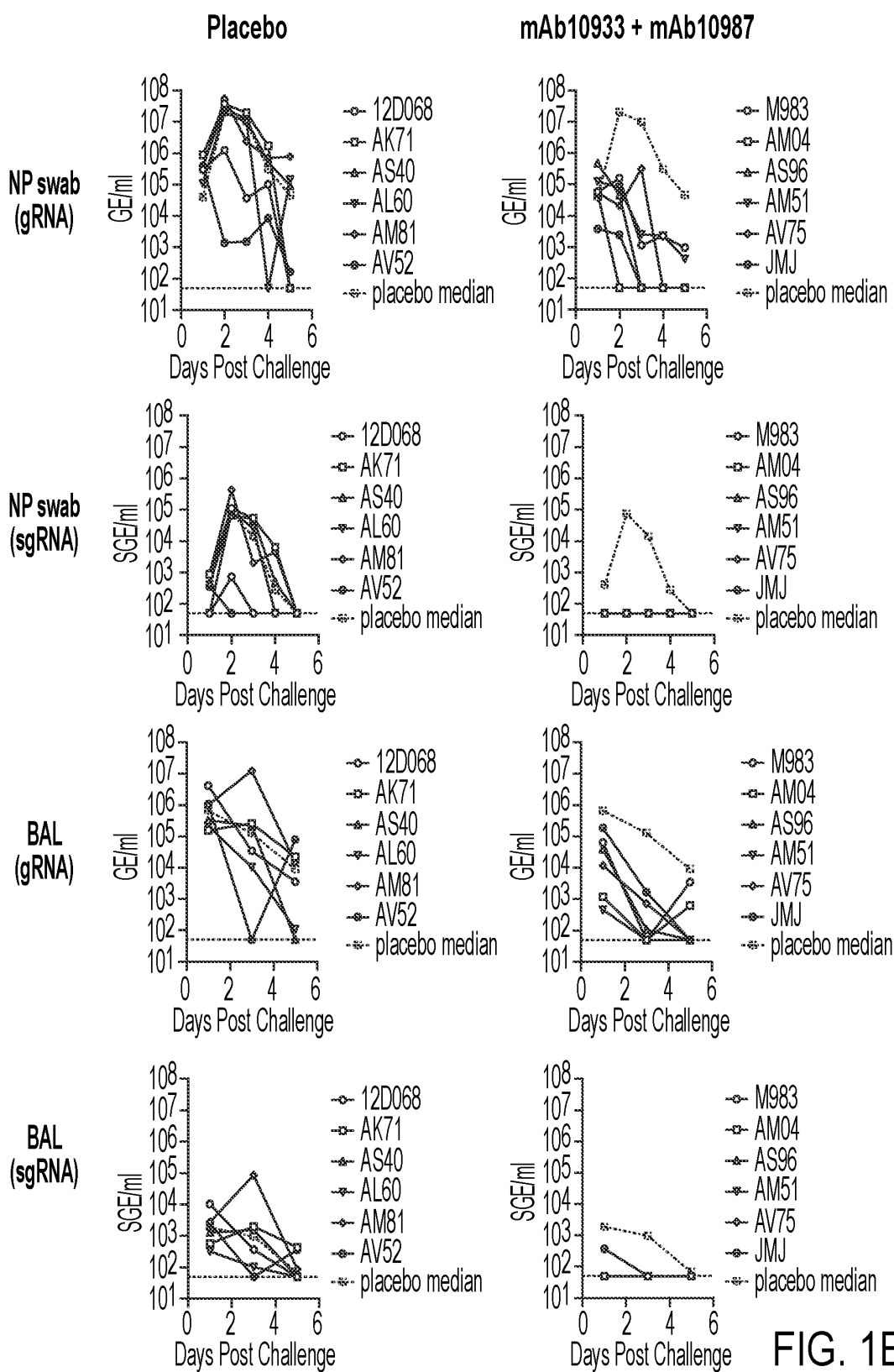


FIG. 1B

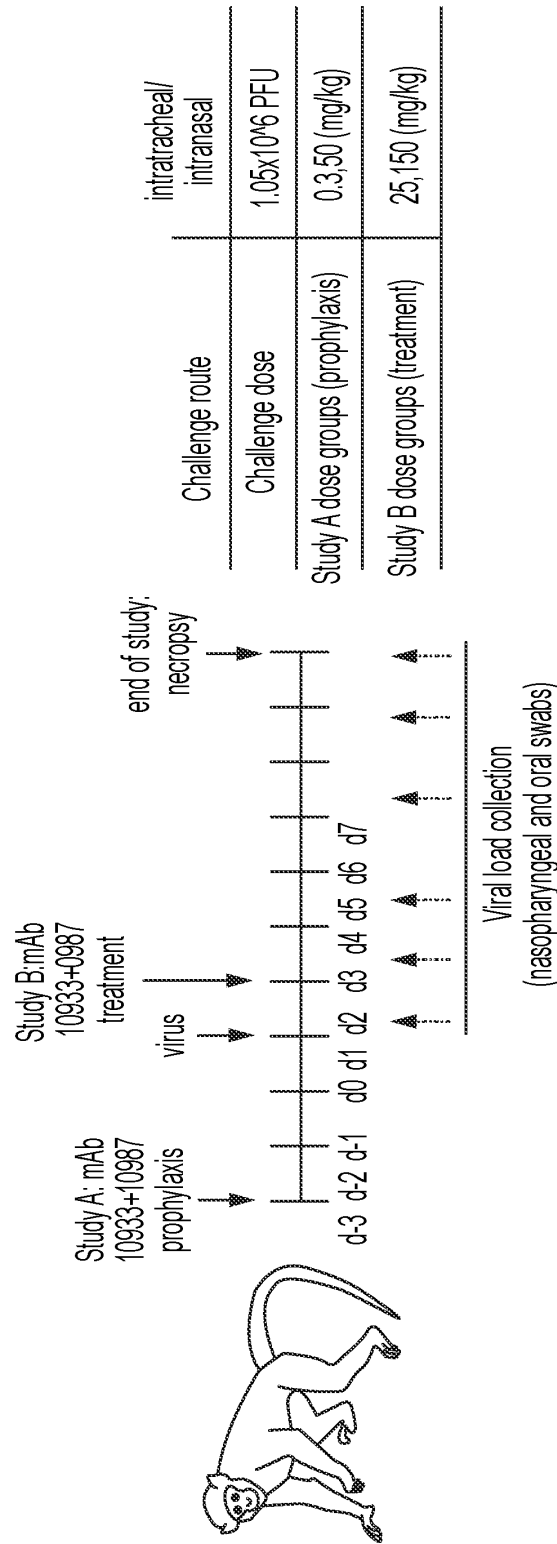


FIG. 2A

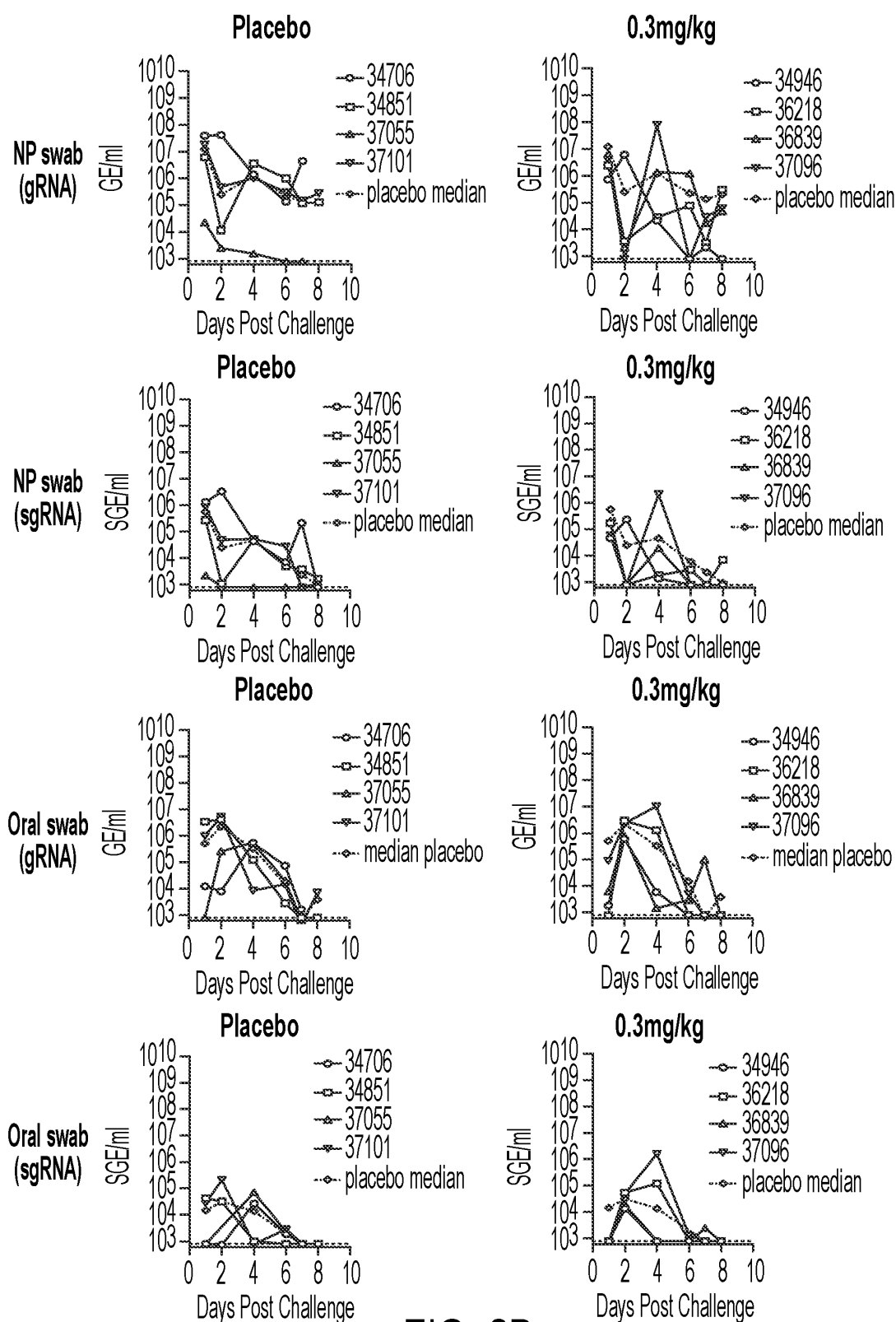


FIG. 2B

SUBSTITUTE SHEET (RULE 26)

5/153

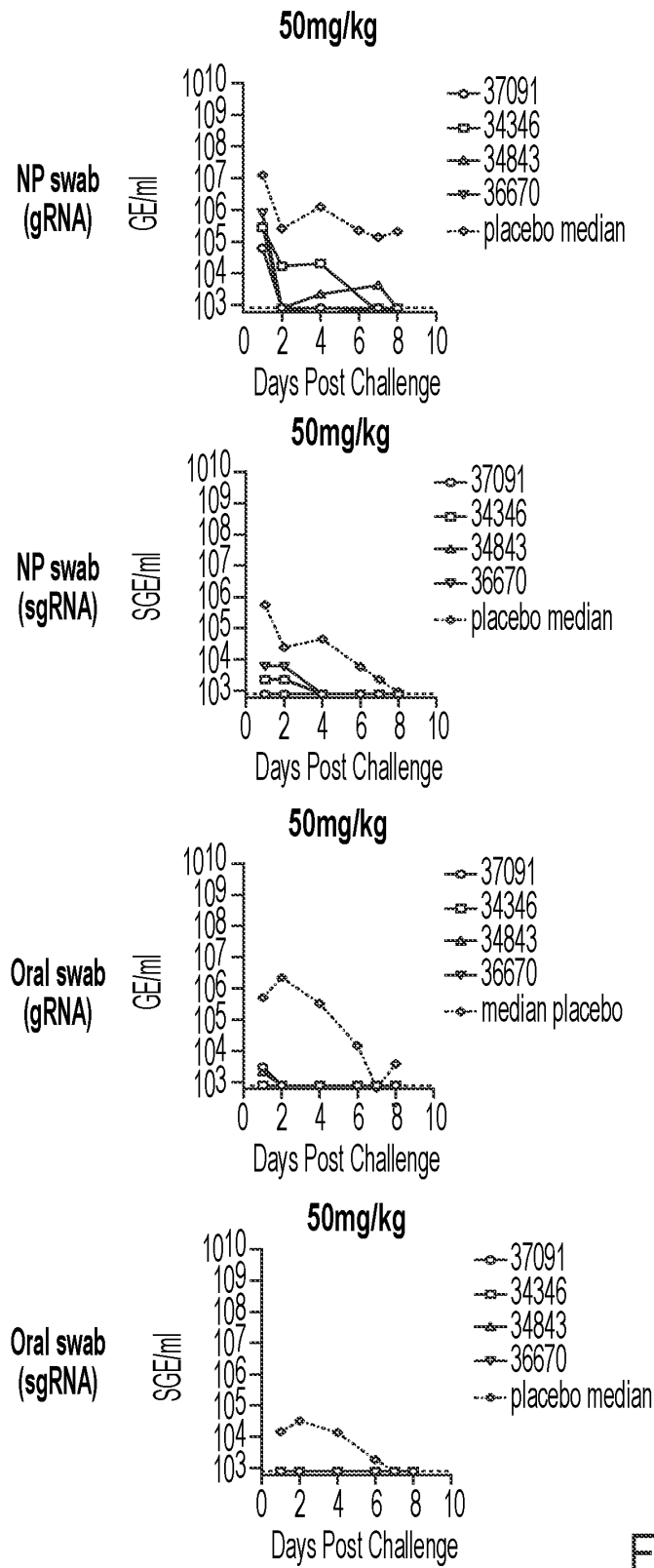


FIG. 2B (Cont.)

6/153

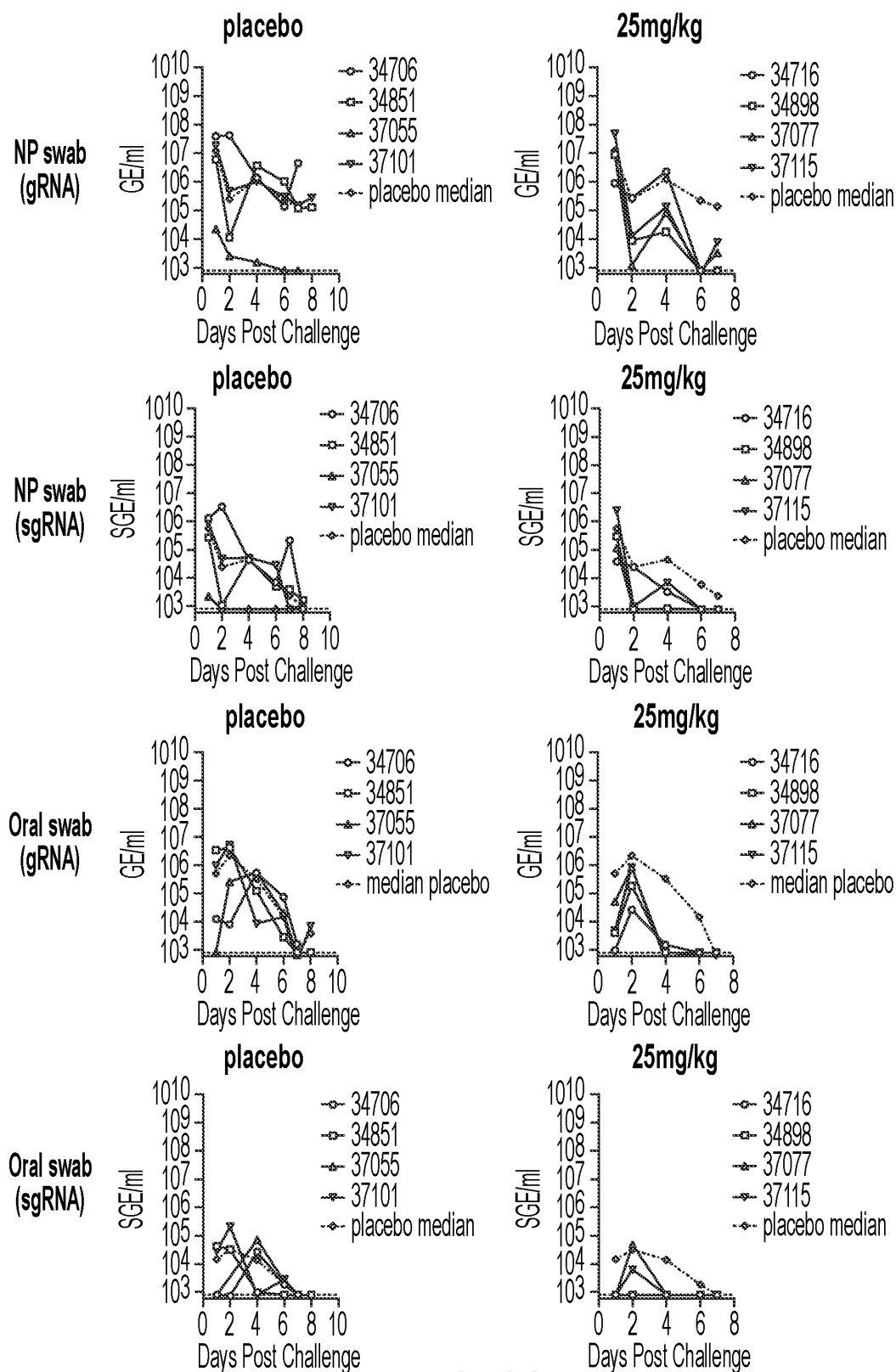


FIG. 2C

SUBSTITUTE SHEET (RULE 26)

7/153

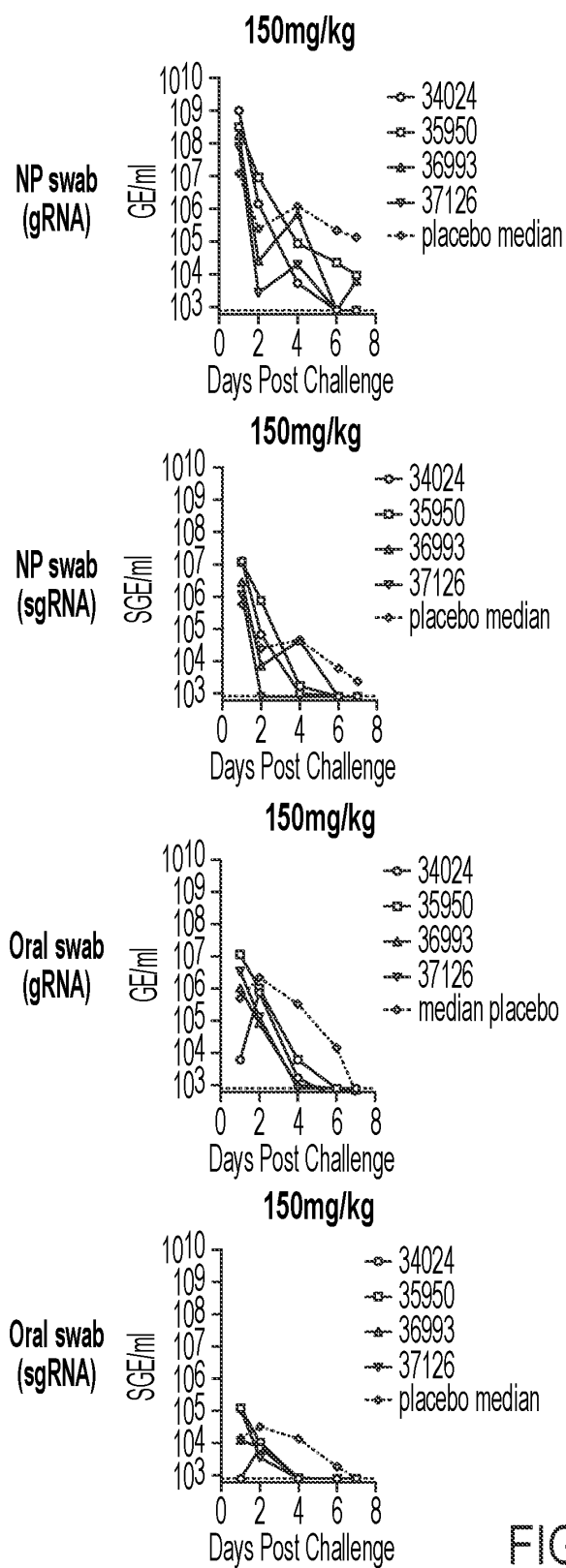


FIG. 2C (Cont.)

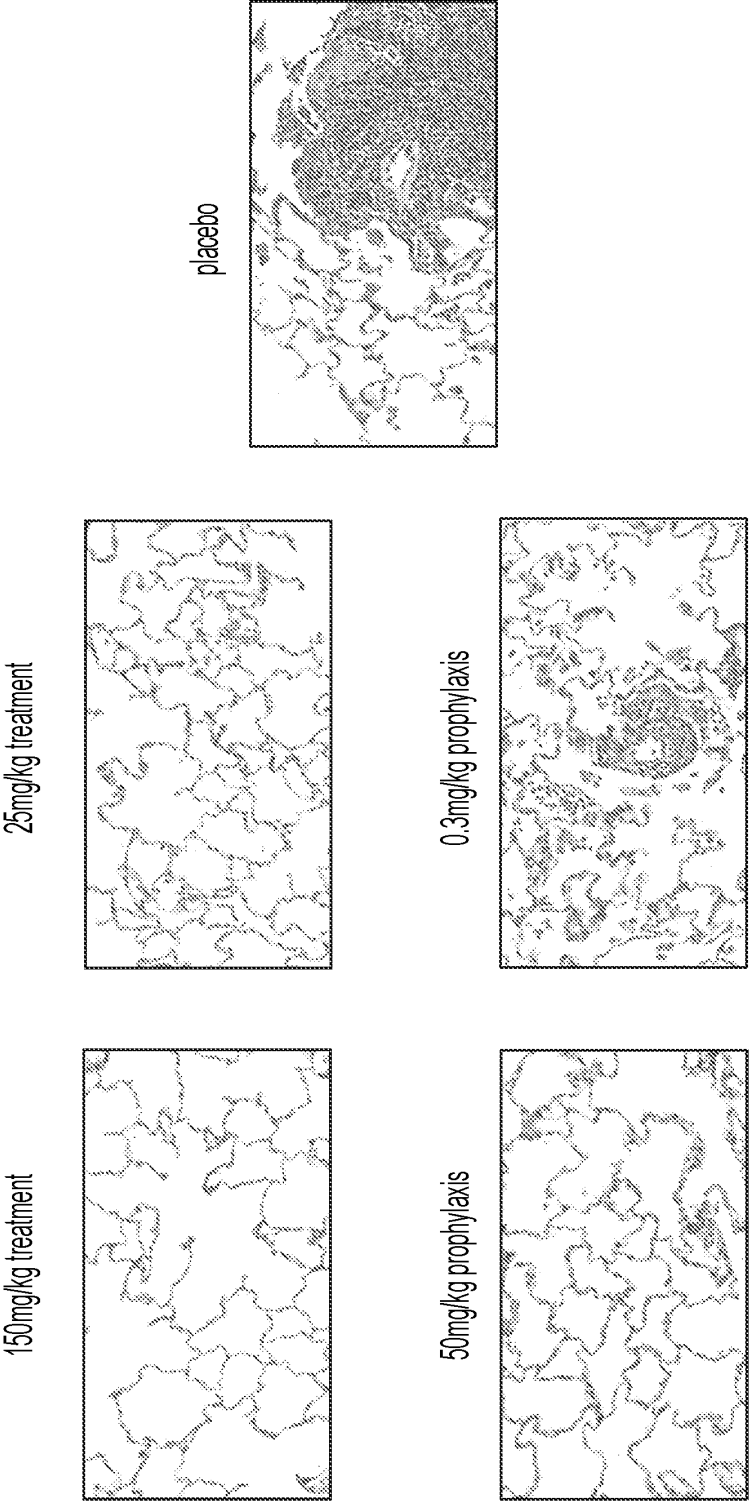


FIG. 2D

9/153

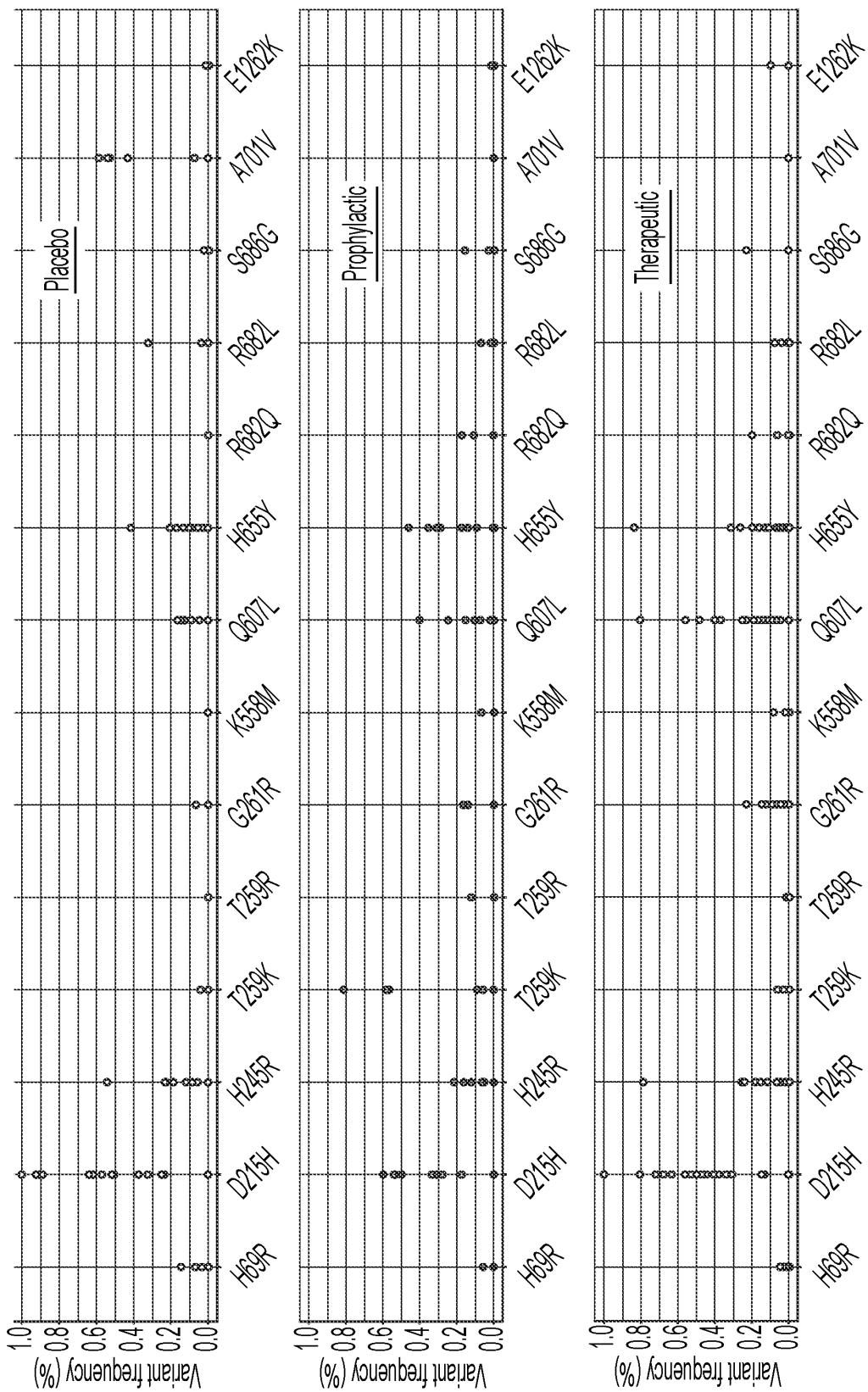
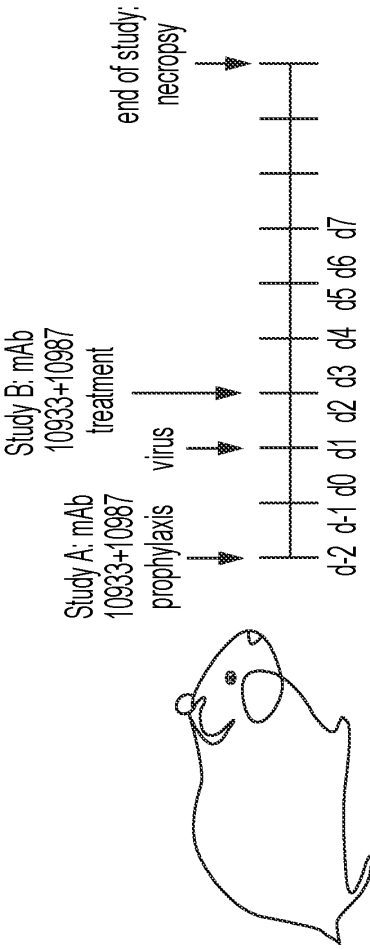


FIG. 3A

Genomic position	21768	22205	22296	22338	22338	22343	23235	23382	23525	23607	23607	23618	23664	25346
Reference nucleotide	A	G	A	C	C	G	A	A	C	G	G	A	C	G
Variant nucleotide	G	C	G	A	G	C	T	T	T	A	T	G	T	A
Gene name	Spike	Spike	Spike	Spike	Spike	Spike	Spike	Spike	Spike	Spike	Spike	Spike	Spike	Spike
Gene position	206	643	734	776	776	781	1673	1820	1963	2045	2045	2056	2102	3784
Mutation nature	nSNP	nSNP	nSNP	nSNP	nSNP	nSNP	nSNP	nSNP	nSNP	nSNP	nSNP	nSNP	nSNP	nSNP
Amino acid position	69	215	245	259	259	261	558	607	655	682	682	686	701	1262
Reference amino acid	H	D	H	T	T	G	K	Q	H	R	R	S	A	E
Variant amino acid	R	H	R	K	R	R	M	L	Y	Q	L	G	V	K
Inoculum	1%	39%	1%	1%	0%	1%	0%	14%	3%	0%	0%	2%	0%	0%
Placebo group	0%-14%	0%-100%	0%-55%	0%-4%	0%	0%-6%	0%	0%-16%	0%-41%	0%	0%-32%	0%-3%	0%-58%	0%-1%
Prophylactic group	0%-6%	0%-60%	0%-21%	0%-81%	0%-12%	0%-16%	0%-7%	0%-40%	0%-46	0%-17%	0%-6%	0%-16%	0%	0%-2%
Therapeutic group	0%-5%	0%-100%	0%-79%	0%-7%	0%-1%	0%-23%	0%-8%	0%-80%	0%-83%	0%-20%	0%-7%	0%-23%	0%-1%	0%-10%

FIG. 3B



Challenge route	intranasal
Challenge dose	5.6x10 ⁴ PFU
Study A dose groups (prophylaxis)	50, 5, 0.5 (mg/kg)
Study B dose groups (treatment)	50, 5, 0.5 (mg/kg)

FIG. 4A

12/153

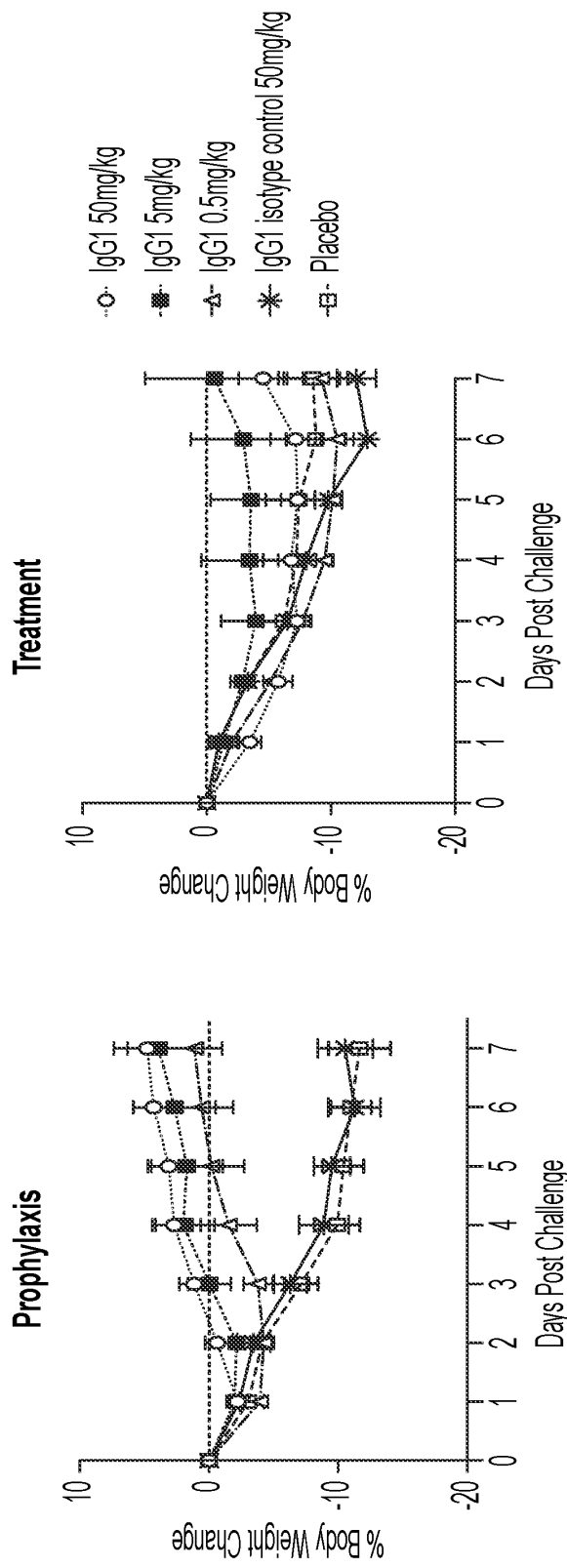


FIG. 4B

13/153

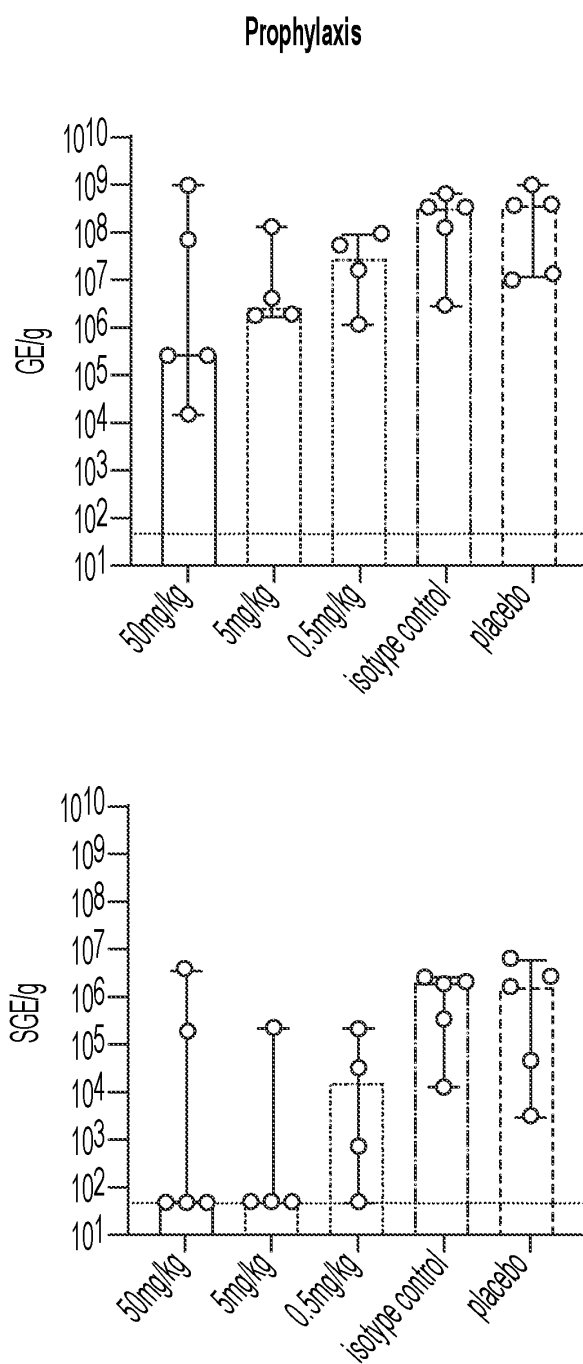


FIG. 4C

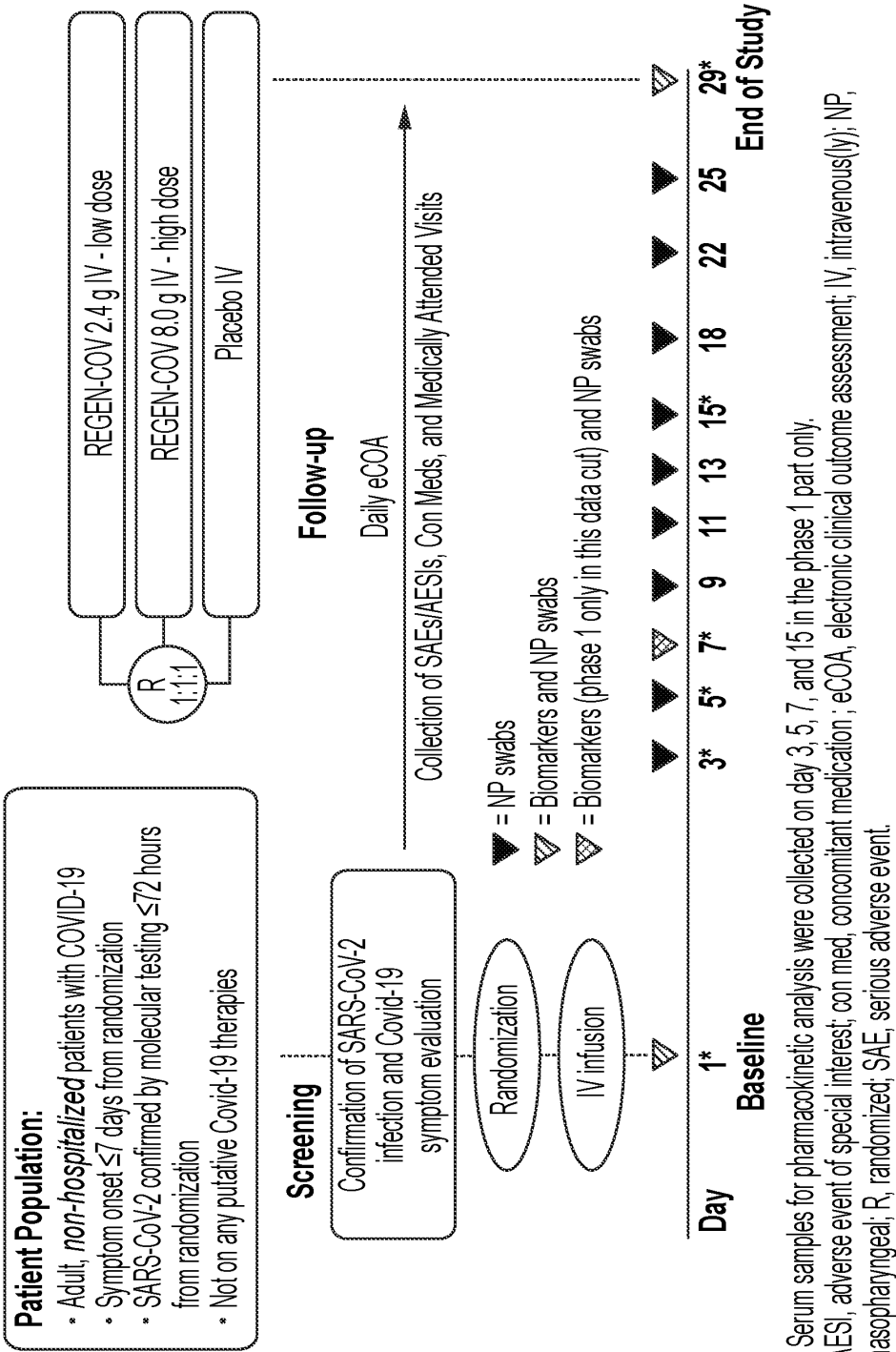


FIG. 5

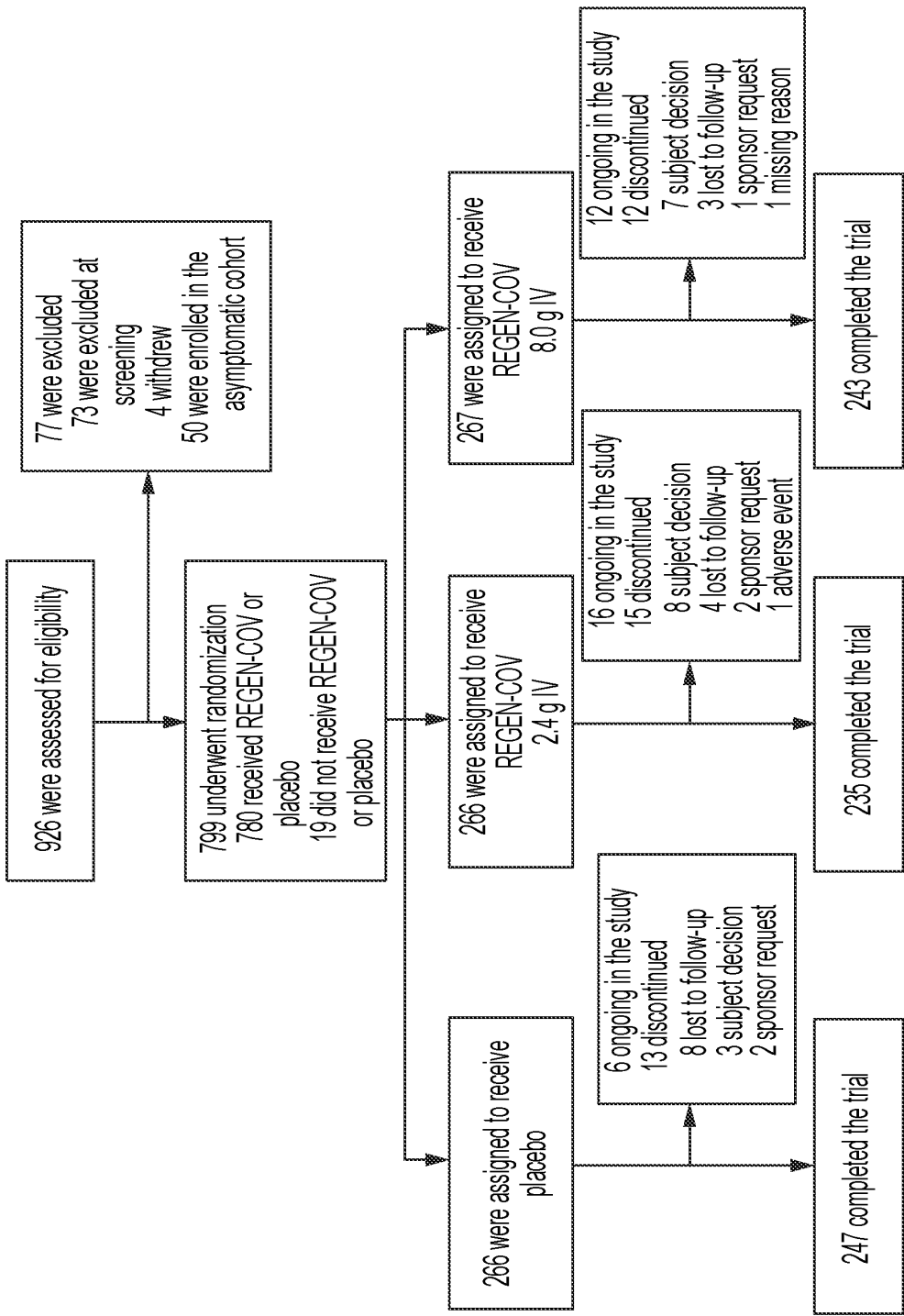


FIG. 6

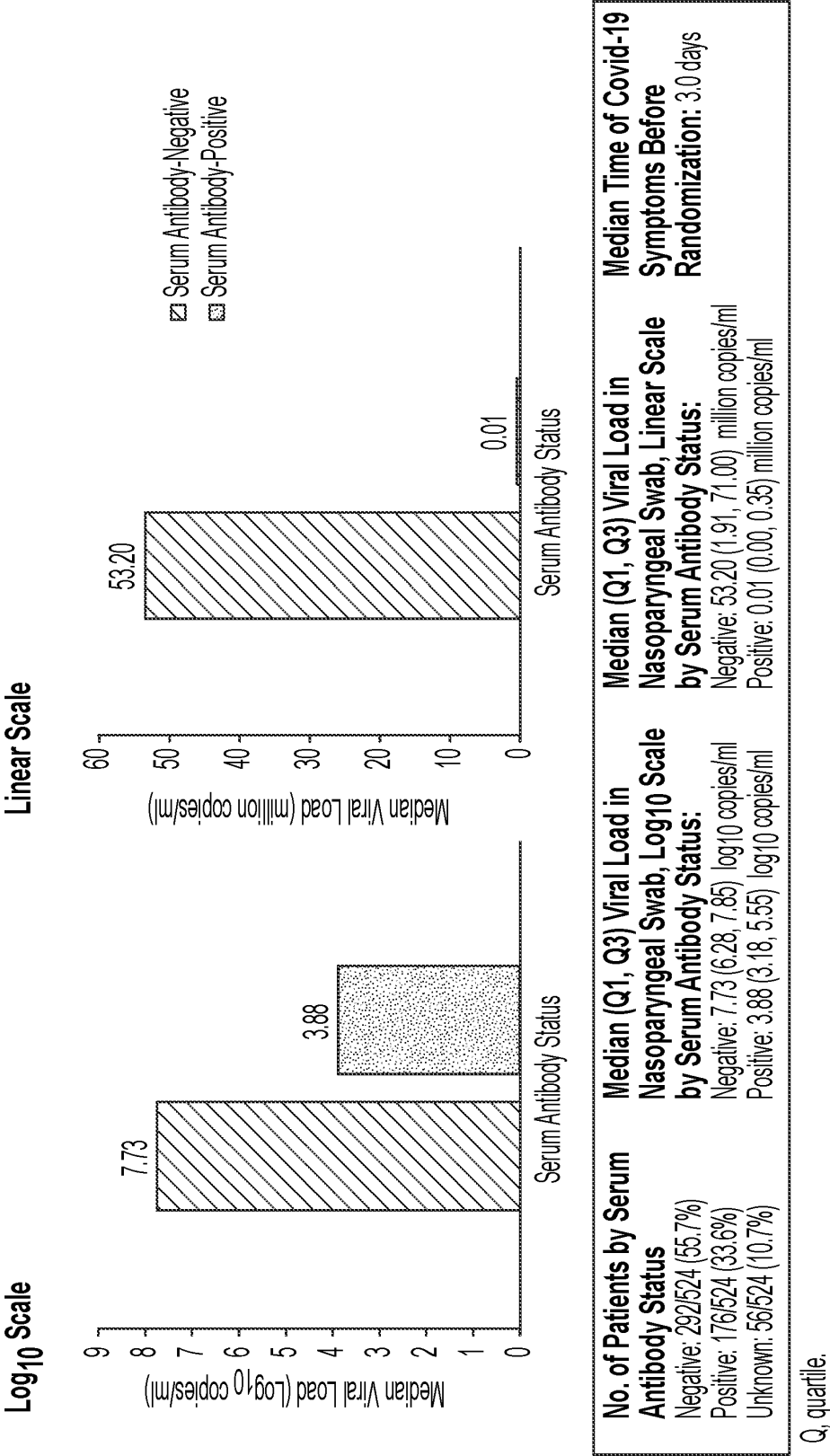


FIG. 7

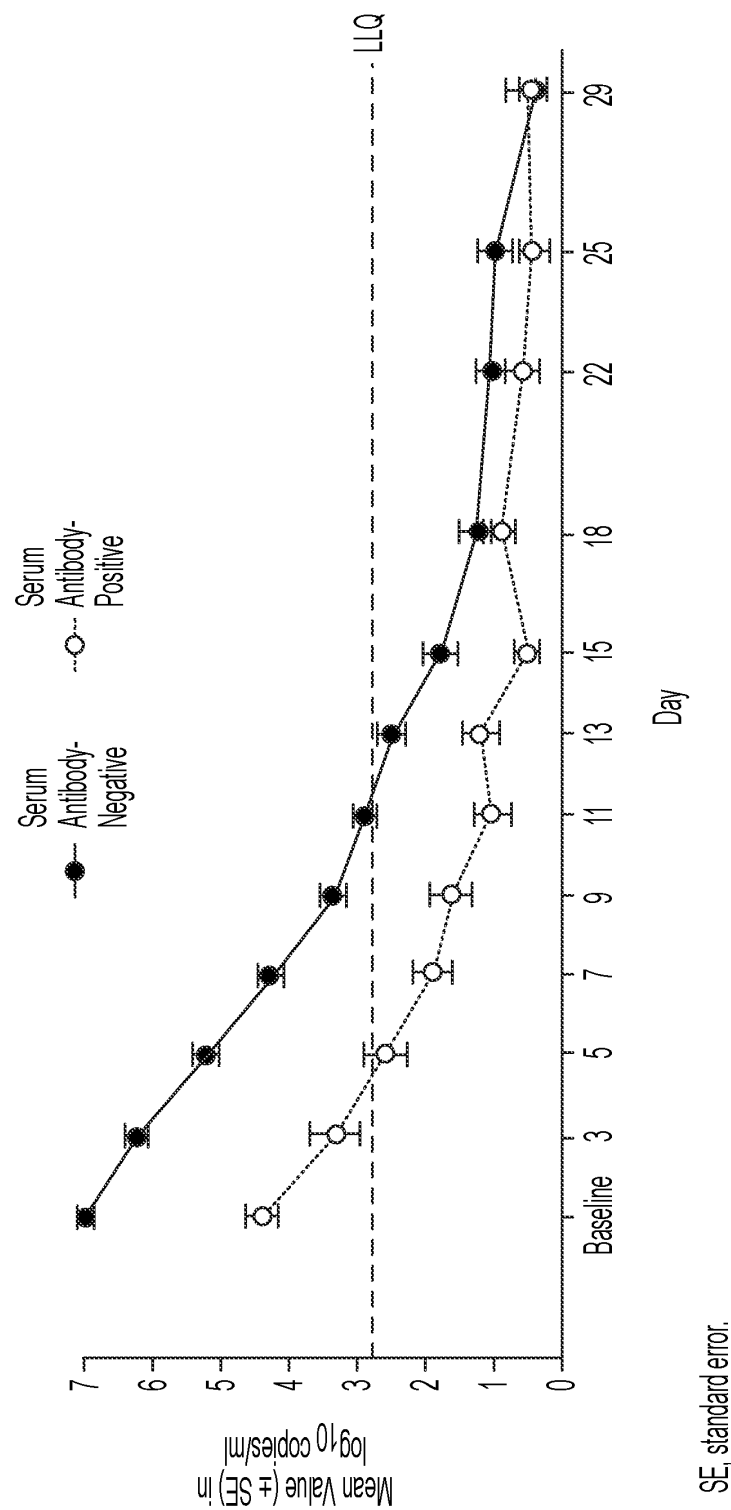


FIG. 8

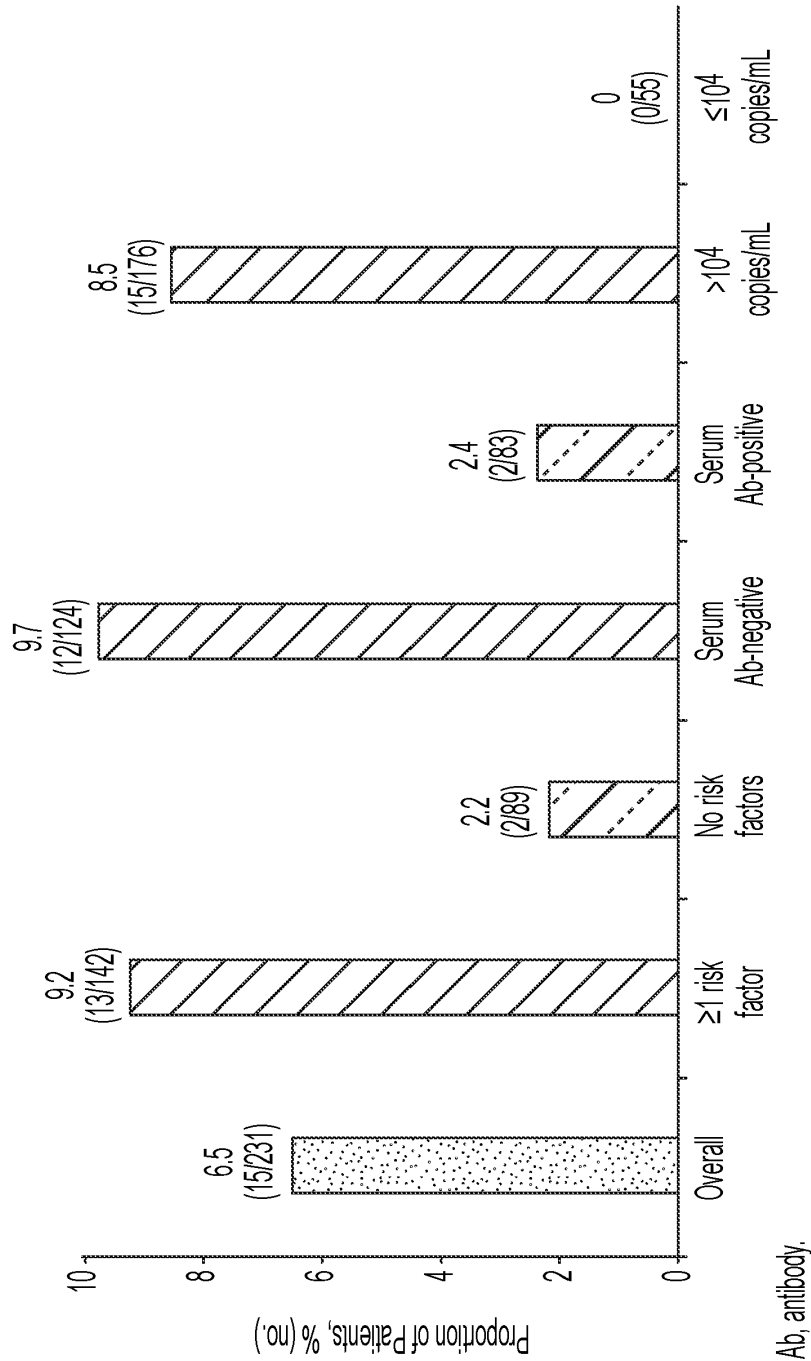


FIG. 9

A. Average Daily Viral Load (log₁₀ copies/mL) Through Day 7 (Analysis Group 2)*

Group	REGEN-COV	Placebo	Time-weighted average change Mean (Standard Error)	Difference (95% CI) P Value
Baseline Viral Load >10⁷ copies/mL				
Combined dose groups vs Placebo (n=185)	-2.13 (0.13)	-1.46 (0.15)		-0.68 (-0.94, -0.41) <0.0001
8000 mg vs Placebo (n=124)	-2.13 (0.16)	-1.46 (0.15)		-0.68 (-0.99, -0.36) <0.0001
2400 mg vs Placebo (n=132)	-2.14 (0.16)	-1.46 (0.15)		-0.68 (-0.99, -0.37) <0.0001
Baseline Viral Load >10⁶ copies/mL				
Combined dose groups vs Placebo (n=237)	-2.06 (0.11)	-1.40 (0.13)		-0.65 (-0.89, -0.41) <0.0001
8000 mg vs Placebo (n=161)	-1.98 (0.13)	-1.40 (0.13)		-0.58 (-0.86, -0.30) <0.0001
2400 mg vs Placebo (n=163)	-2.13 (0.13)	-1.40 (0.13)		-0.73 (-1.01, -0.45) <0.0001
Baseline Seronegative				
Combined dose groups vs Placebo (n=256)	-1.91 (0.08)	-1.18 (0.10)		-0.73 (-0.97, -0.48) <0.0001
Baseline Seropositive				
Combined dose groups vs Placebo (n=137)	-1.32 (0.10)	-1.37 (0.16)		0.05 (-0.32, 0.42) 0.7866
mFAS				
Combined dose groups vs Placebo (n=437)	-1.66 (0.07)	-1.30 (0.09)		-0.36 (-0.56, -0.16) 0.0003

<--Favors REGEN-COV 0.25 0 0.25 Favors Placebo-->

FIG. 10A

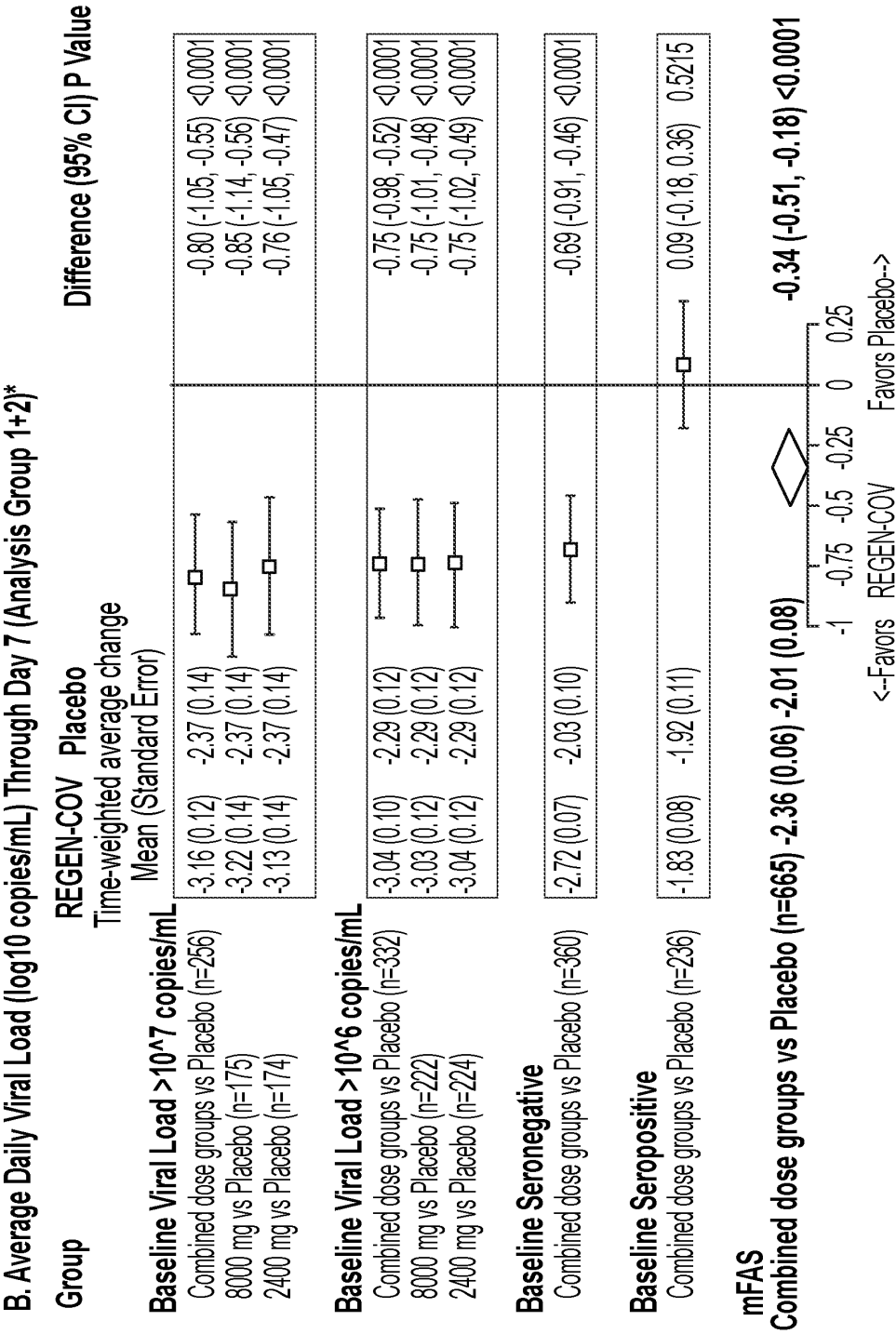
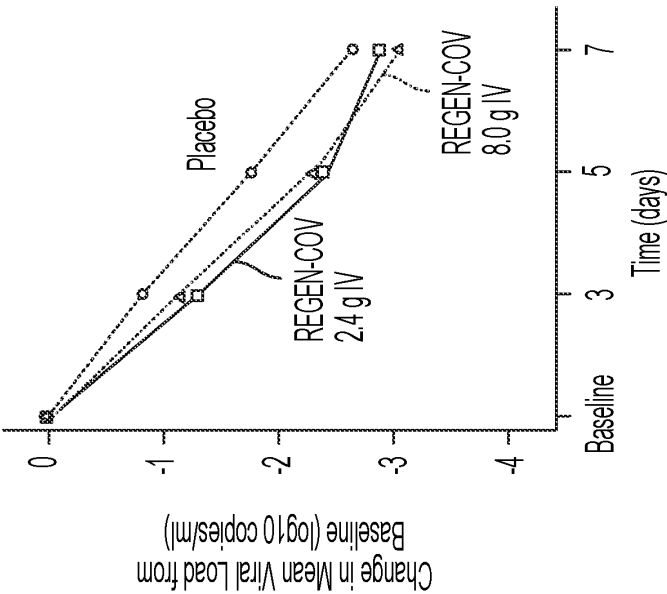


FIG. 10B

* Adjusted analysis of time-weighted average (TWA) daily change from baseline in viral load (log₁₀ copies/mL) was based on Analysis of Covariance (ANCOVA) model with treatment group, country, risk factor, and baseline serology status as fixed effects, and baseline viral load and treatment by baseline viral load as covariates. CI, confidence interval.

A. Viral Load over Time in the Overall Population (mFAS)

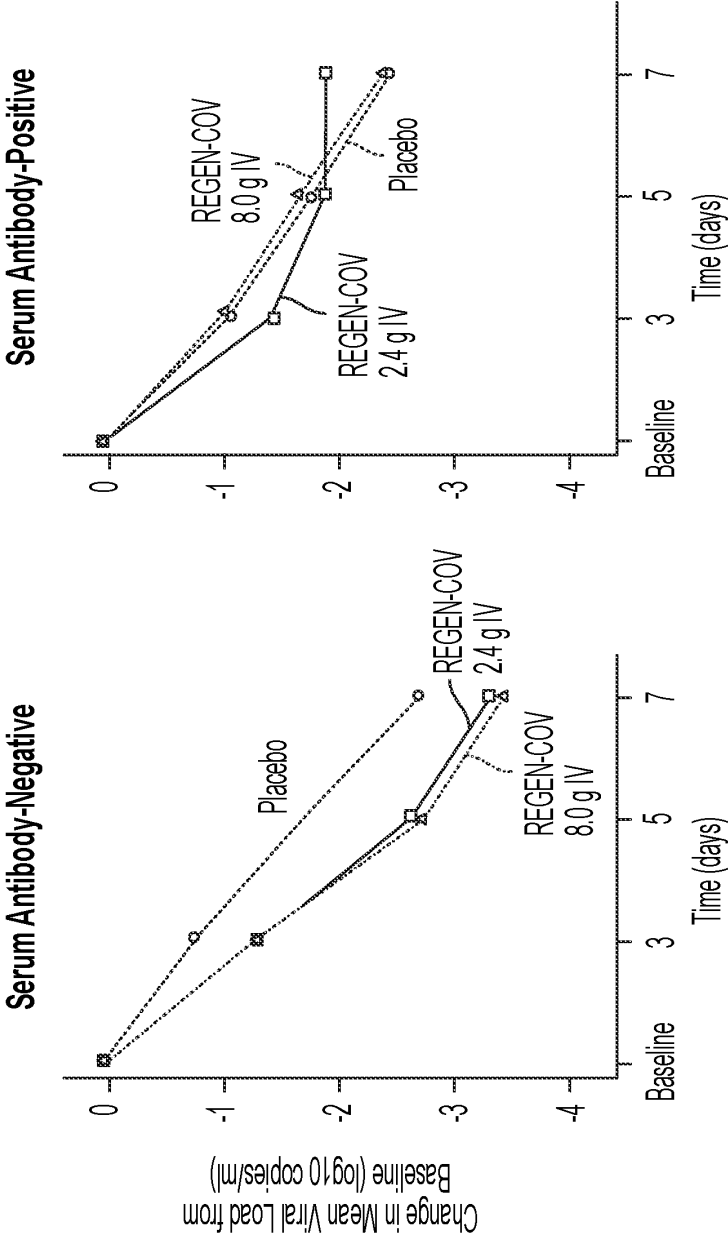


No. at Risk

Placebo	156	136	143	148
REGEN-COV 2.4 g IV	142	132	137	137
REGEN-COV 8.0 g IV	146	135	140	141

FIG. 11

B. Viral Load over Time According to Baseline Antibody Status (mFAS)



No. at Risk

Placebo	94	87	91	93	42	30	40	41
REGEN-COV 2.4 g IV	83	78	80	90	46	42	46	45
REGEN-COV 8.0 g IV	79	73	78	77	50	49	50	60

FIG. 11 (Cont.)

C. Viral Load over Time According to Baseline Viral Load Category (mFAS)

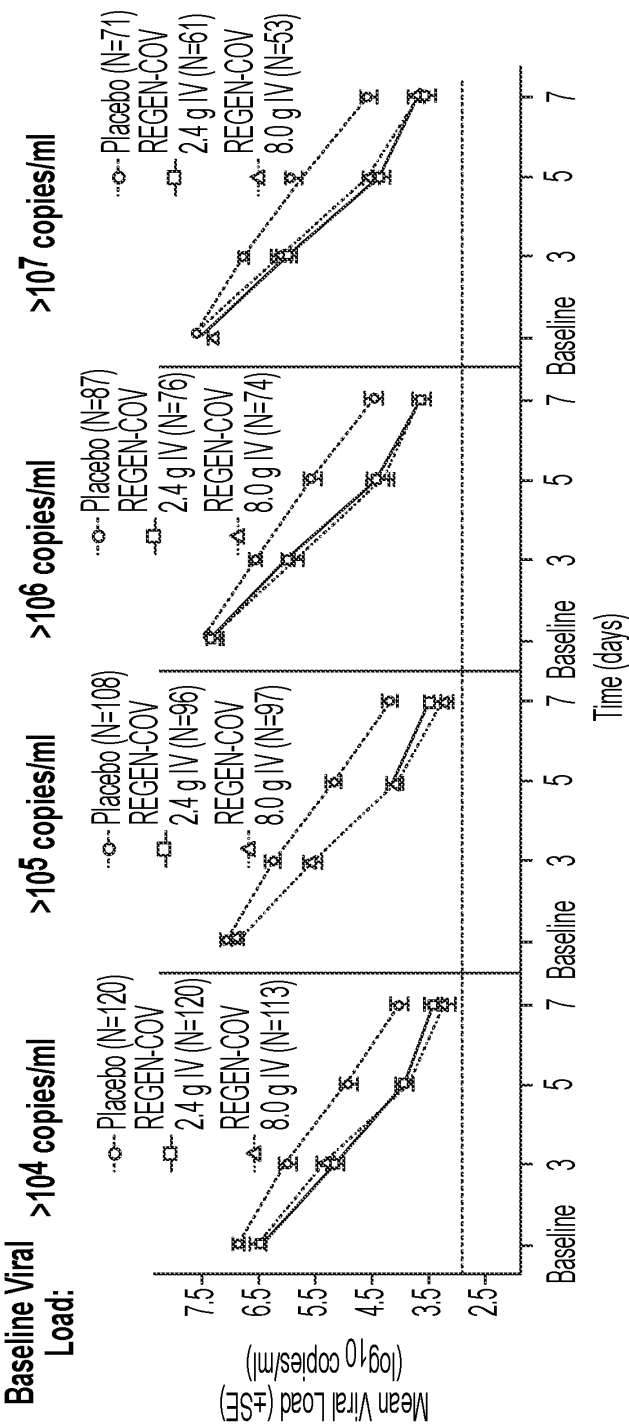
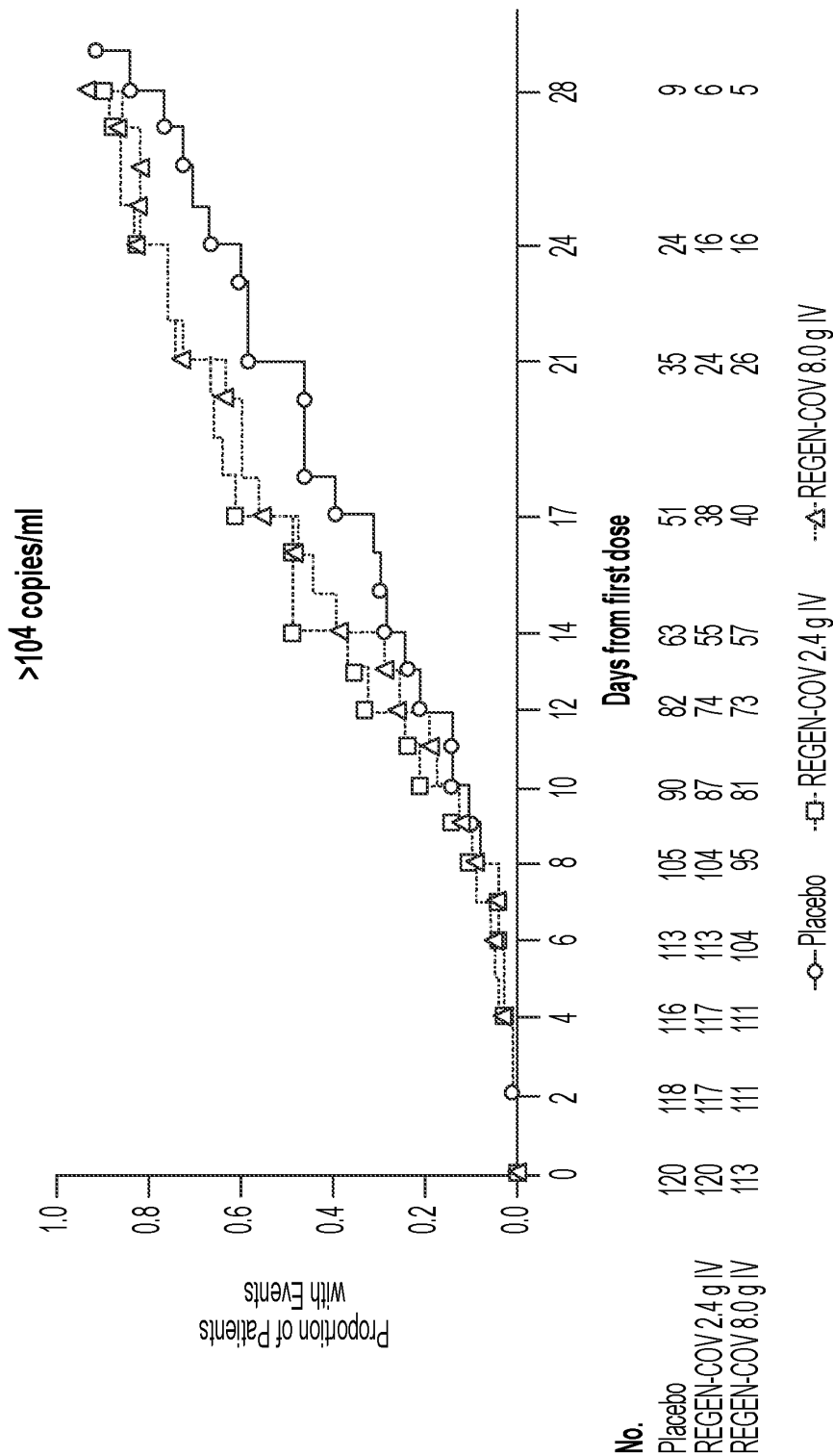
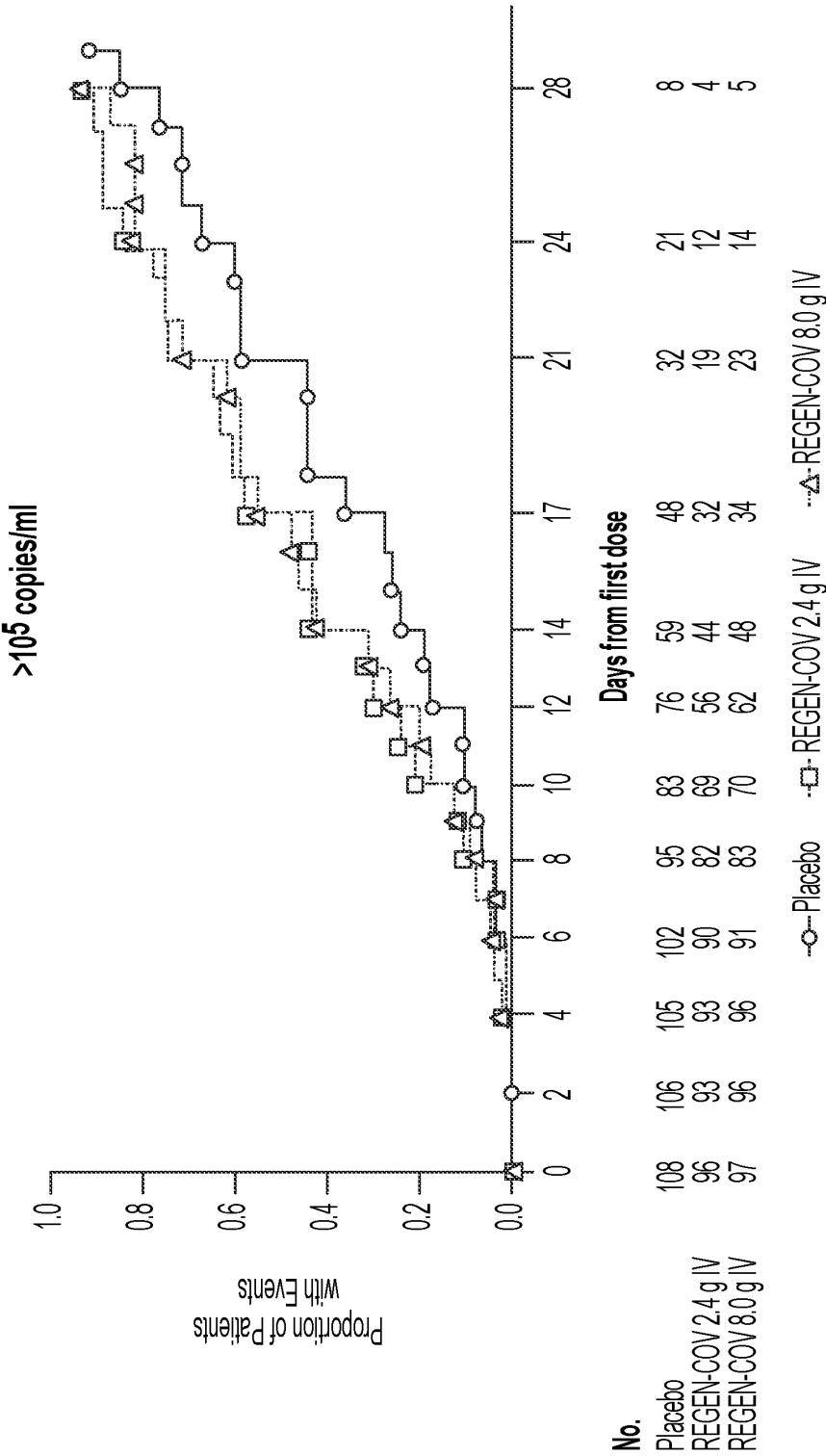


FIG. 11 (Cont.)



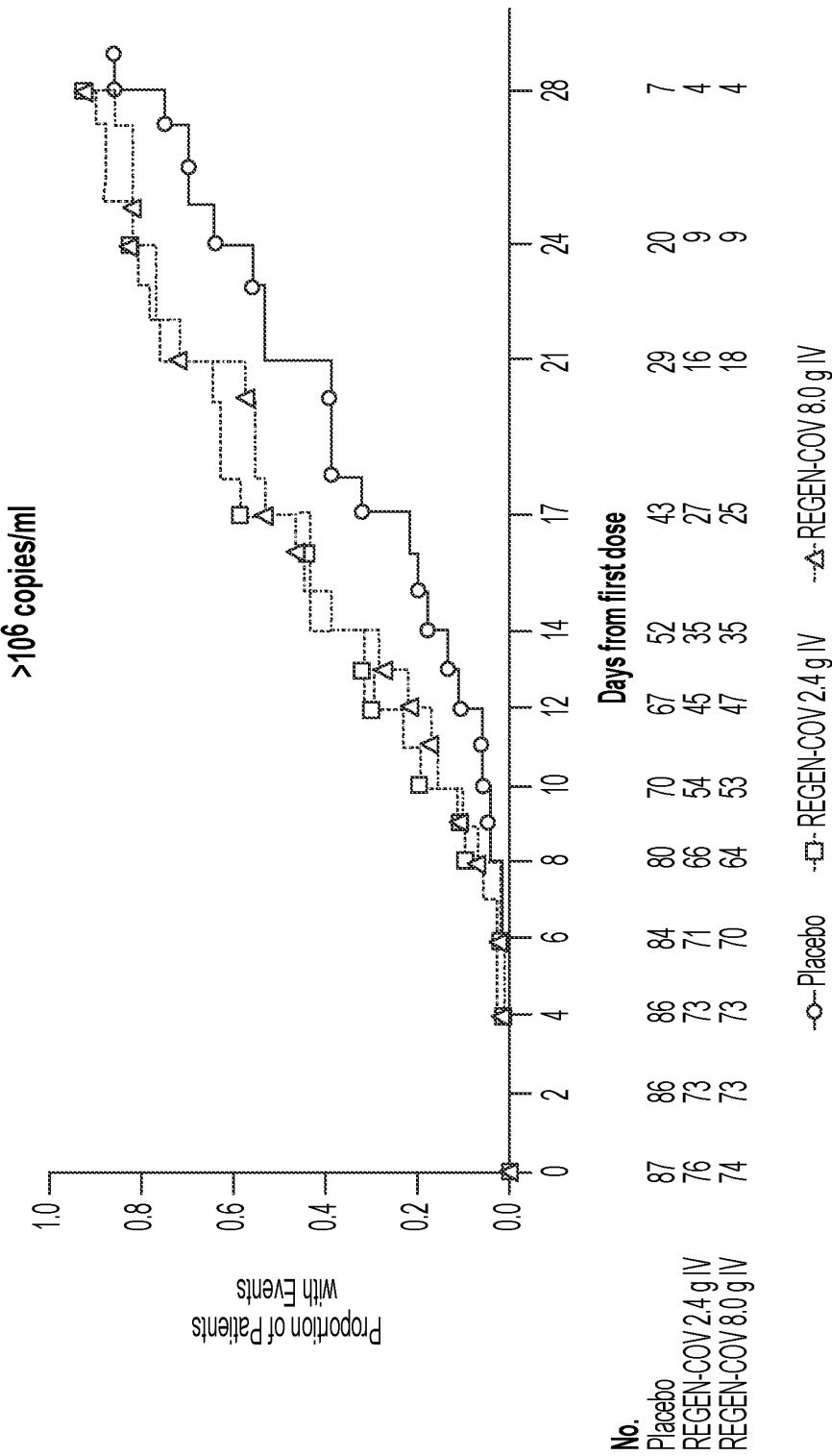
The time to negative RT-qPCR in NP swabs with no subsequent positive RT-qPCR for analysis group 2 is shown above.
IV, intravenous(y); NP, nasopharyngeal; RT-qPCR, quantitative real-time RT-PCR.

FIG. 12



The time to negative RT-qPCR in NP swabs with no subsequent positive RT-qPCR for analysis group 2 is shown above. IV, intravenous(y); NP, nasopharyngeal; RT-qPCR, quantitative real-time RT-PCR.

FIG. 12 (Cont.)



The time to negative RT-qPCR in NP swabs with no subsequent positive RT-qPCR for analysis group 2 is shown above.
IV, intravenous(y); NP, nasopharyngeal; RT-qPCR, quantitative real-time RT-PCR.

FIG. 12 (Cont.)

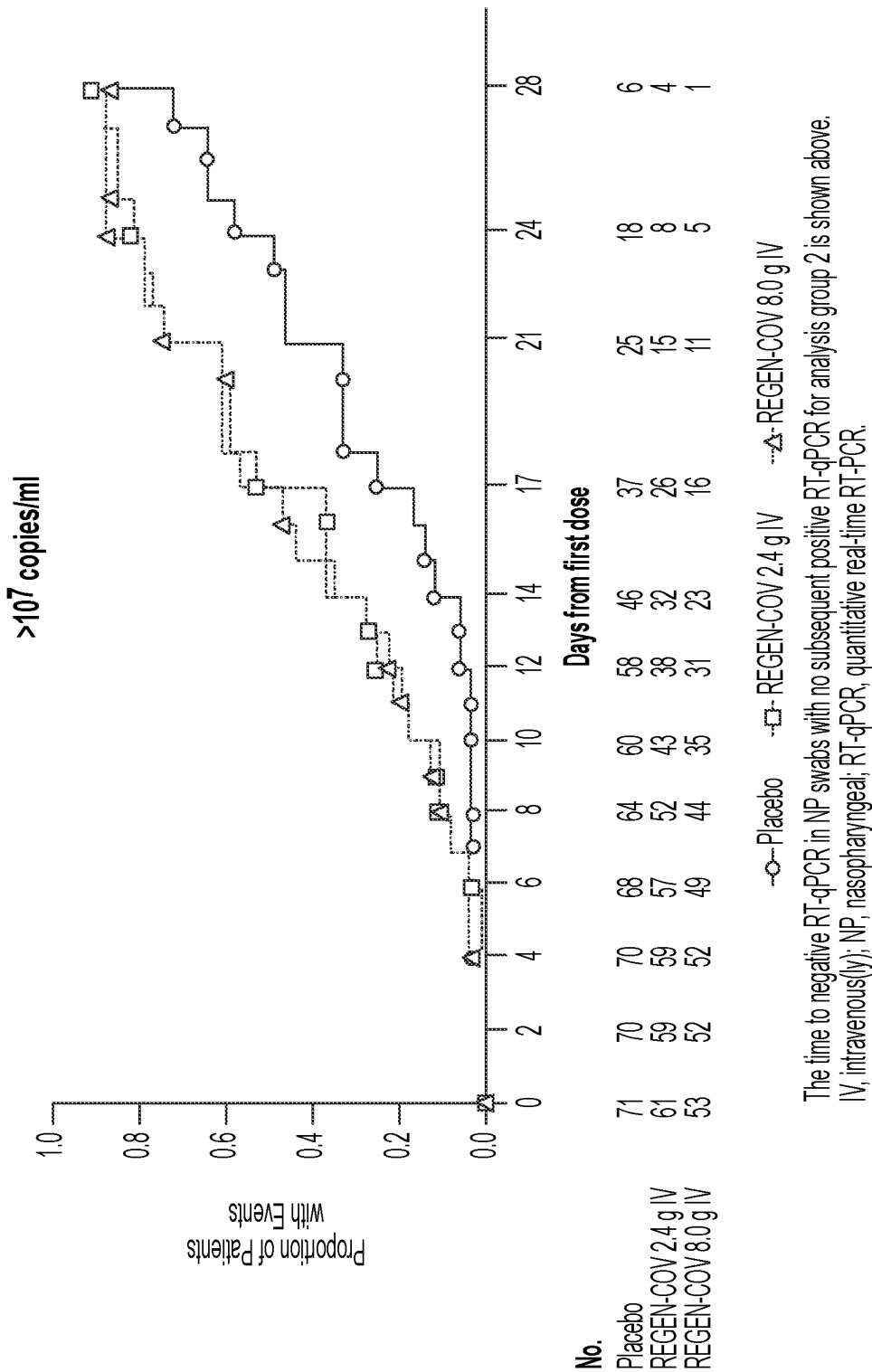
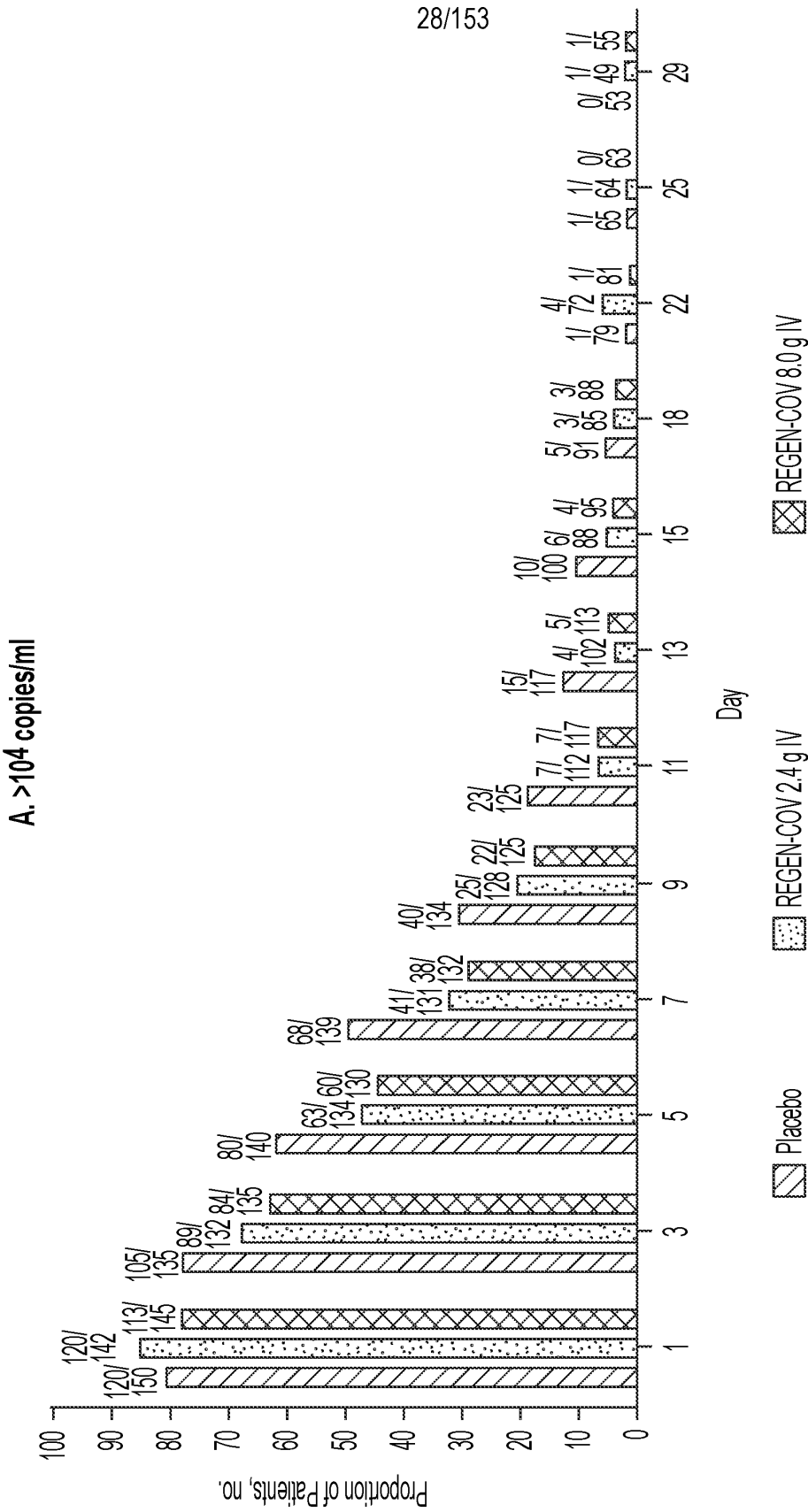
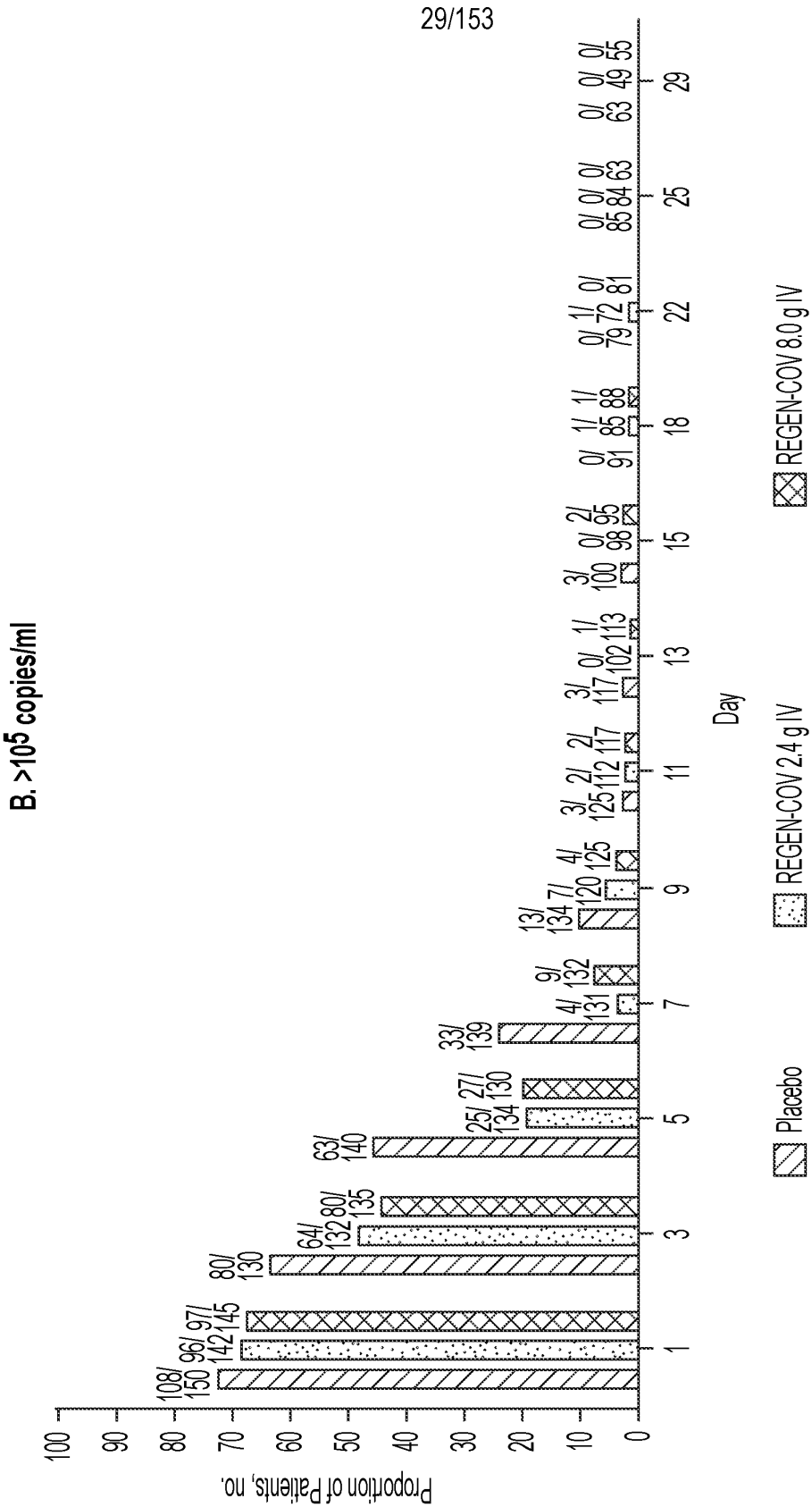


FIG. 12 (Cont.)



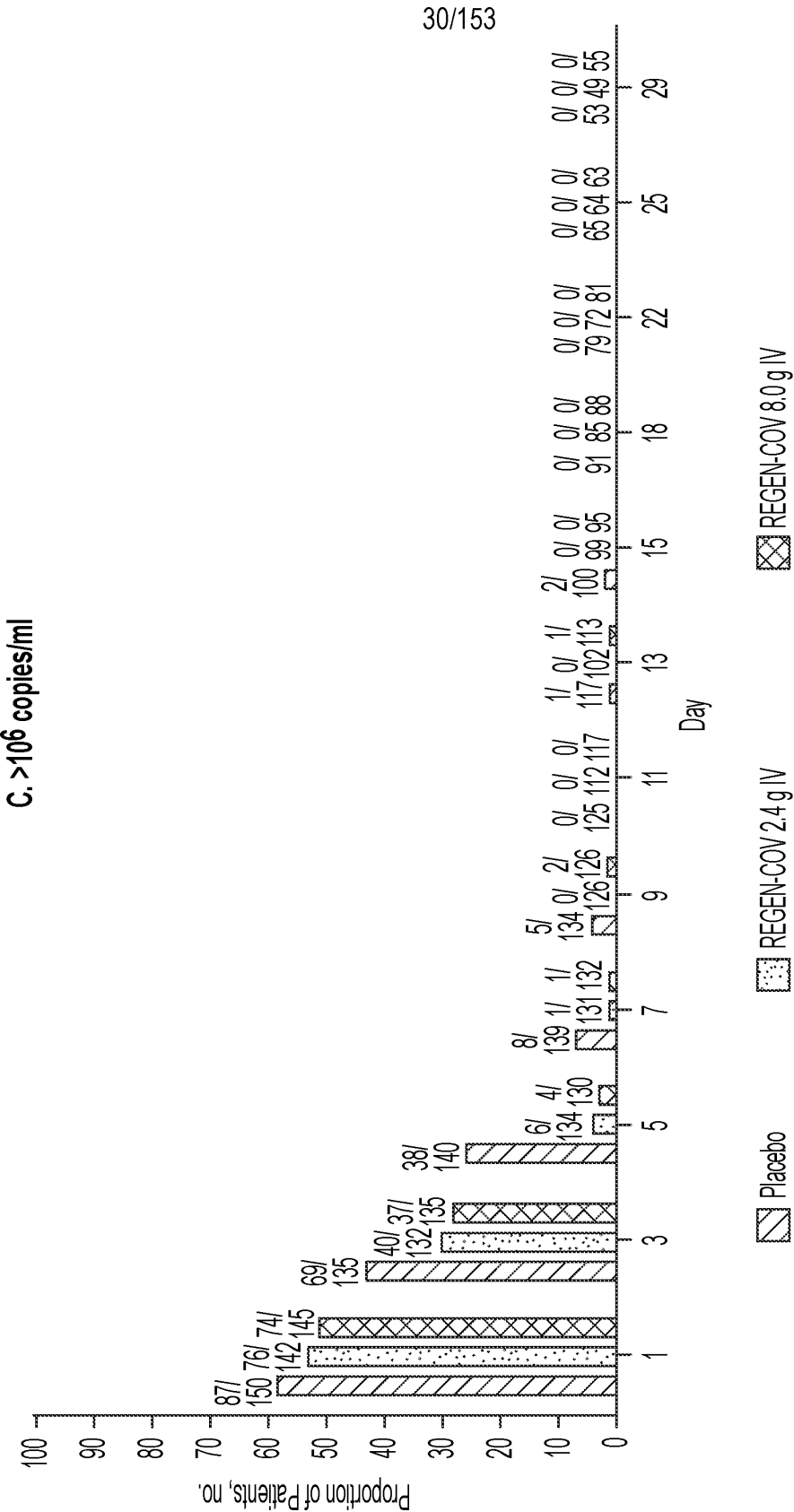
The proportion of patients at each visit with a viral load greater than 10^4 (A) 10^5 (B) 10^6 (C) 10^7 (D) is shown above. IV, intravenous(y).

FIG. 13



The proportion of patients at each visit with a viral load greater than 10⁴ (A) 10⁵ (B) 10⁶ (C) 10⁷ (D) is shown above.
IV, intravenous(y).

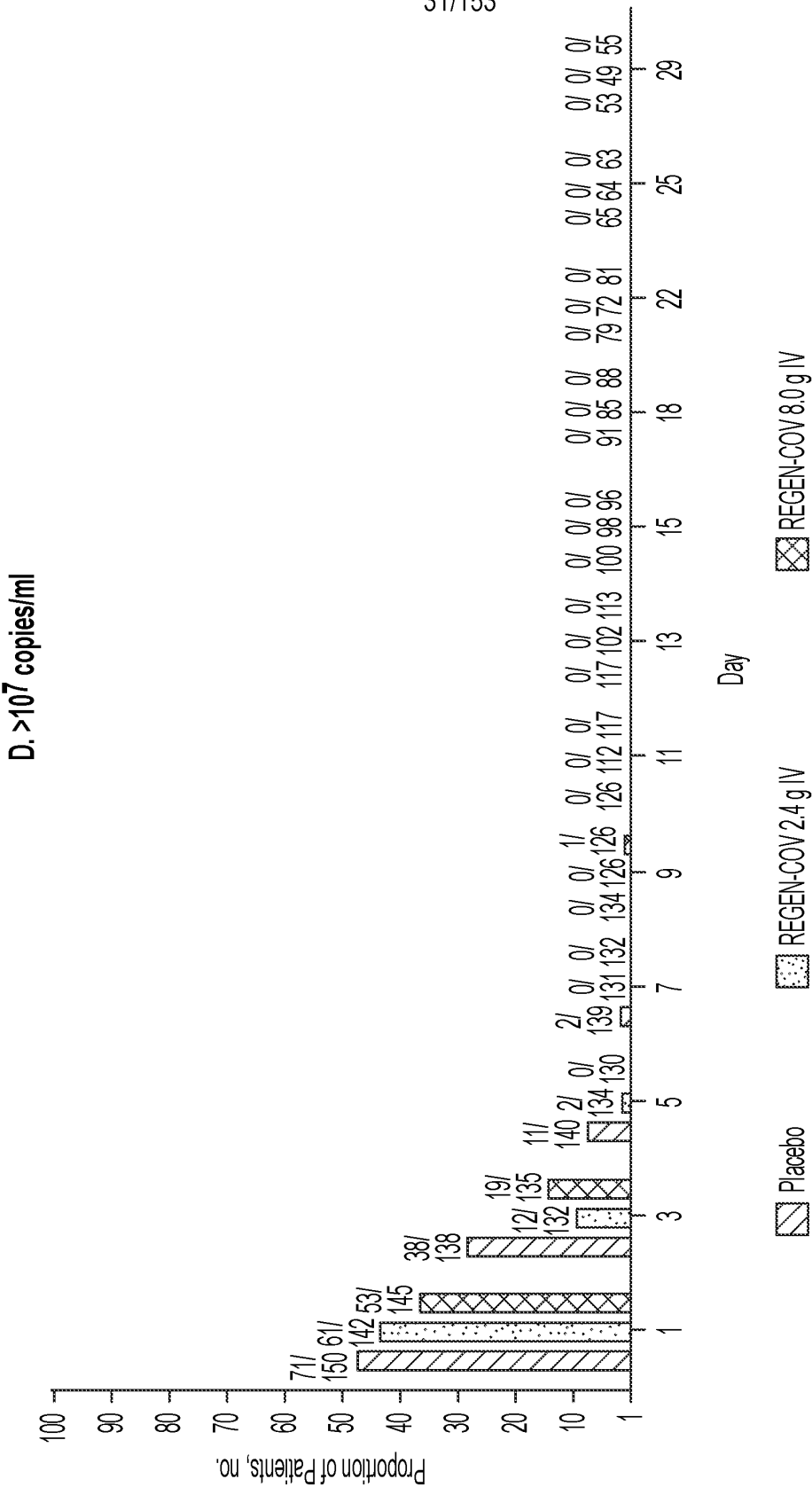
FIG. 13 (Cont.)



The proportion of patients at each visit with a viral load greater than 10⁴ (A) 10⁵ (B) 10⁶ (C) 10⁷ (D) is shown above. IV, intravenous(ly).

FIG. 13 (Cont.)

31/153



The proportion of patients at each visit with a viral load greater than 10⁴ (A) 10⁵ (B) 10⁶ (C) 10⁷ (D) is shown above.
IV, intravenous(y).

FIG. 13 (Cont.)

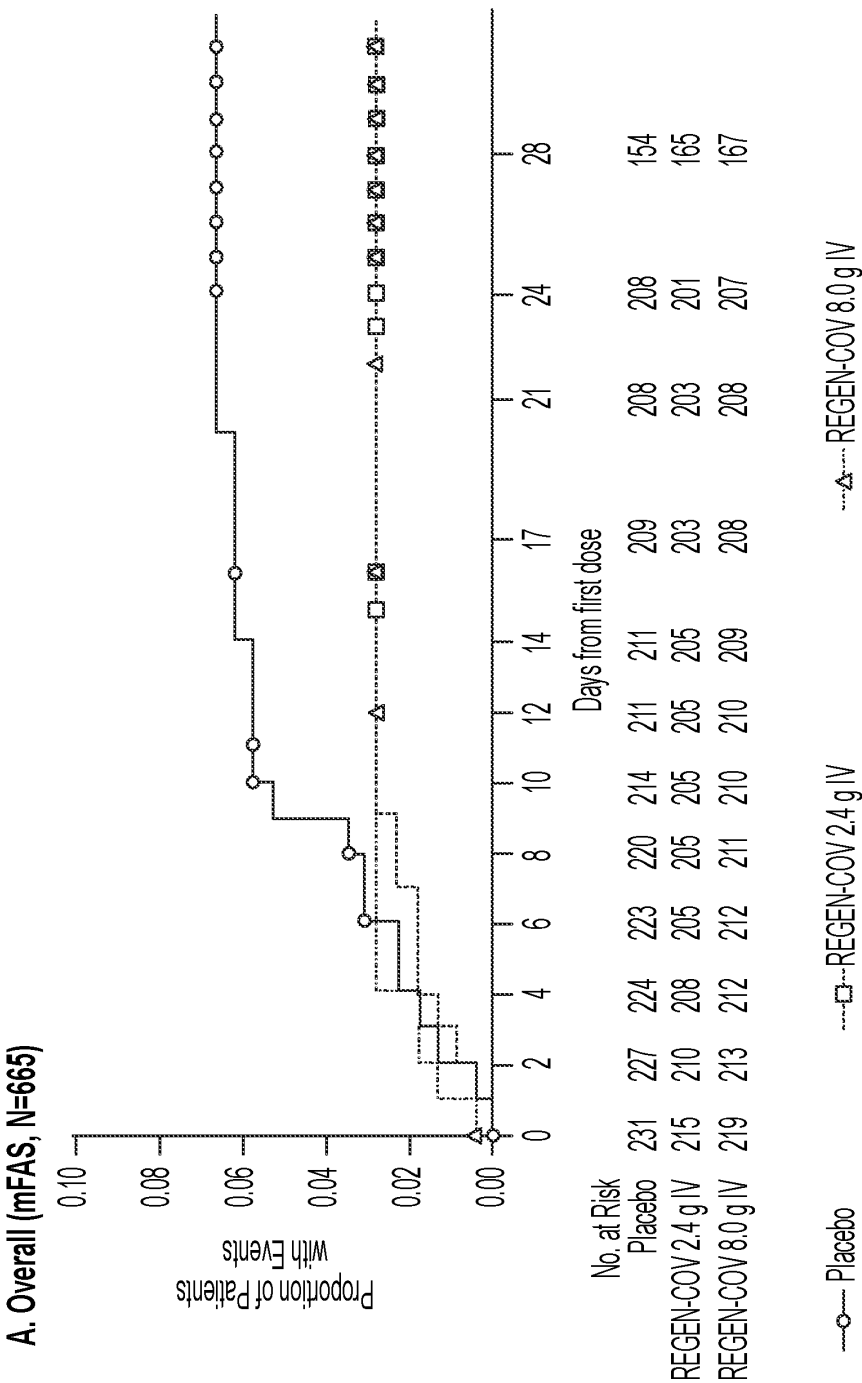


FIG. 14A

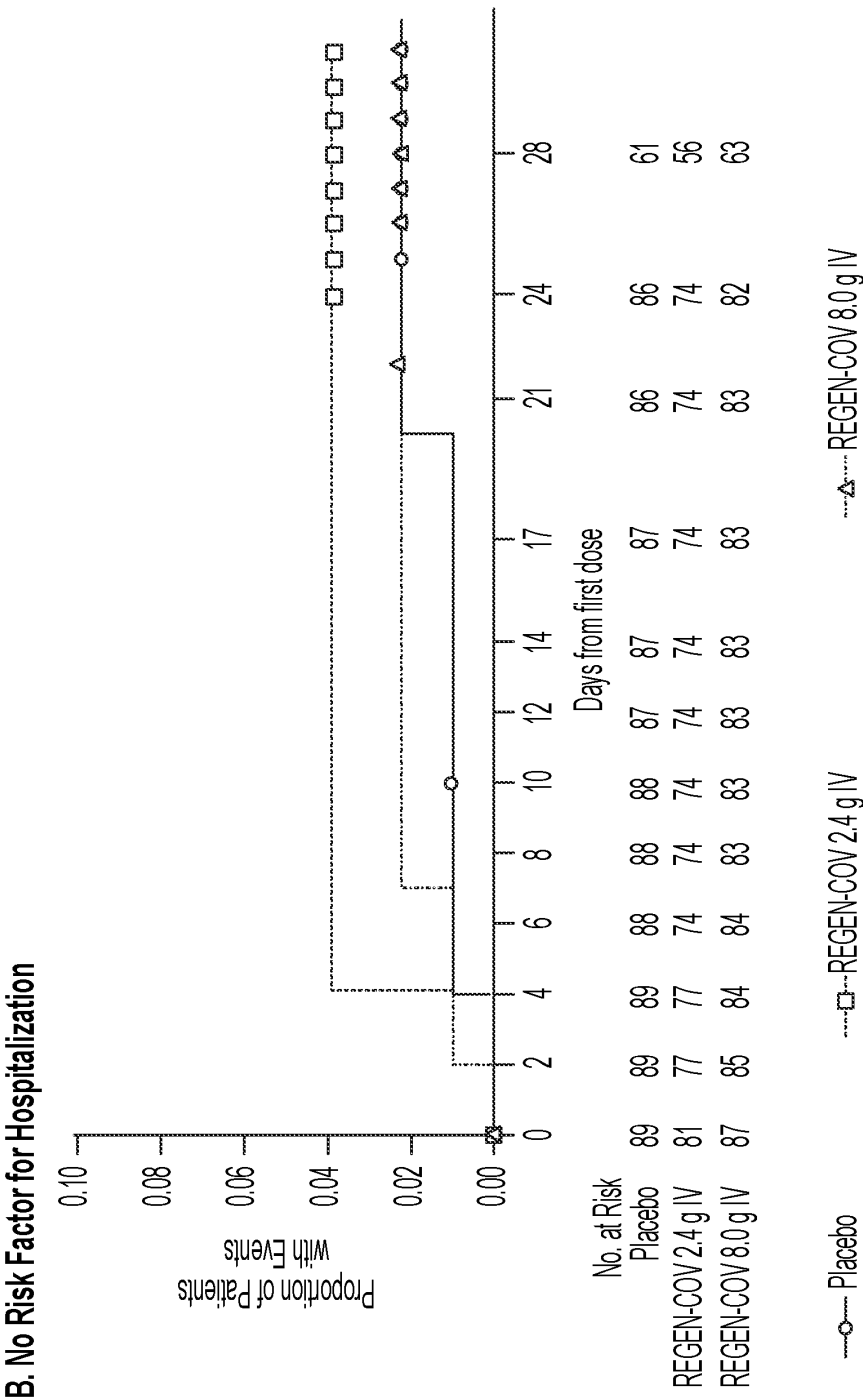


FIG. 14B

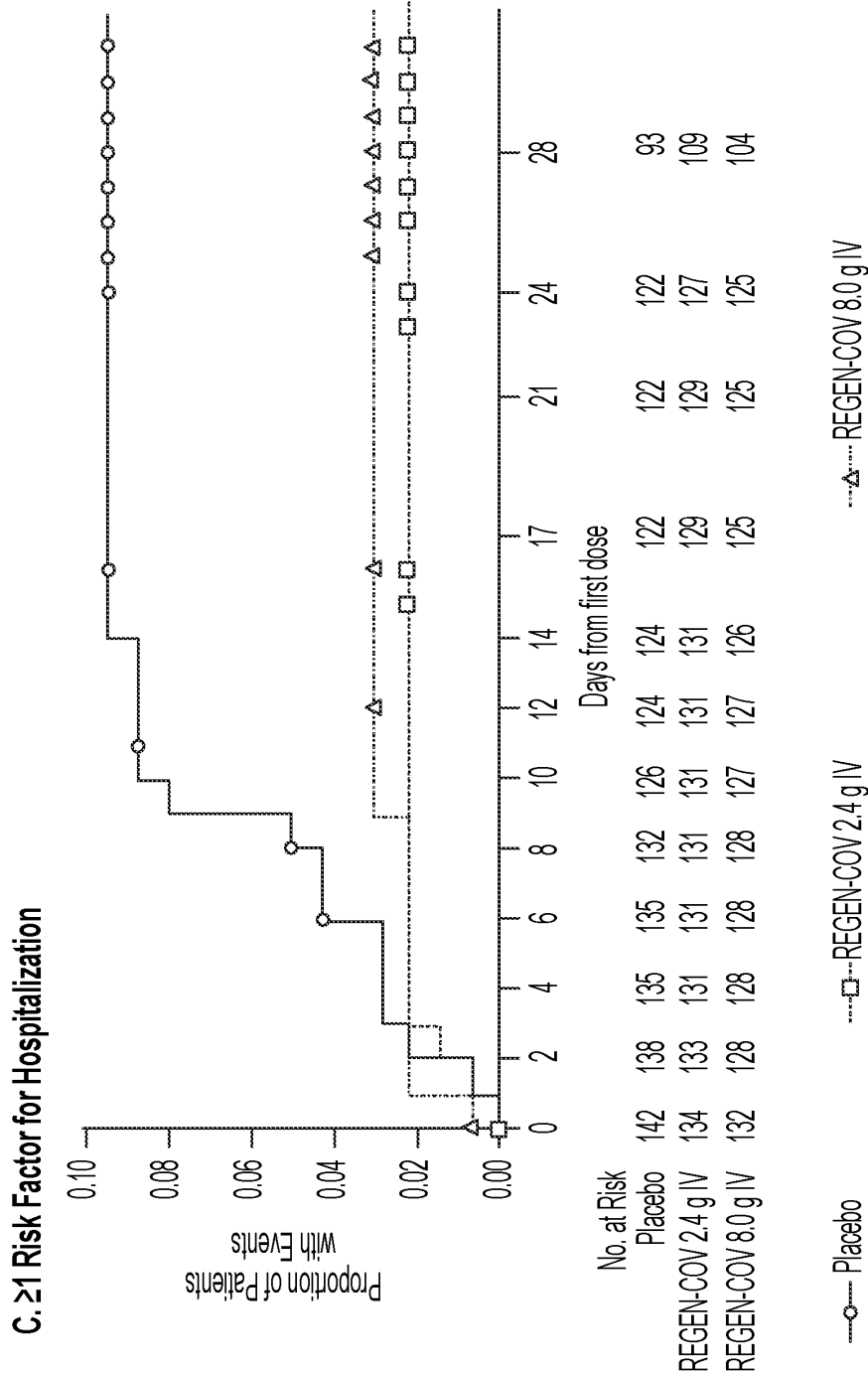


FIG. 14C

A. Viral Load Over Time in Patients With and Without ≥ 1 Covid-19-related MAVs

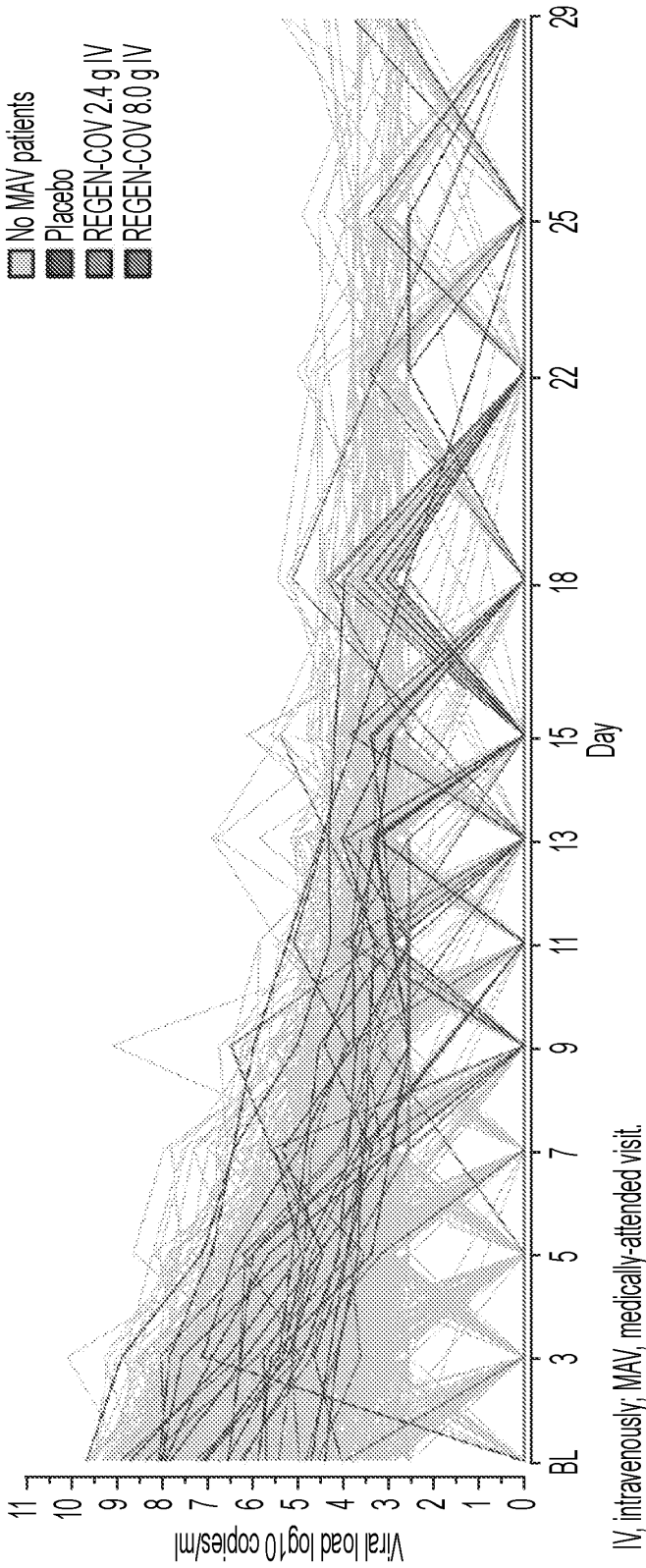


FIG. 15A

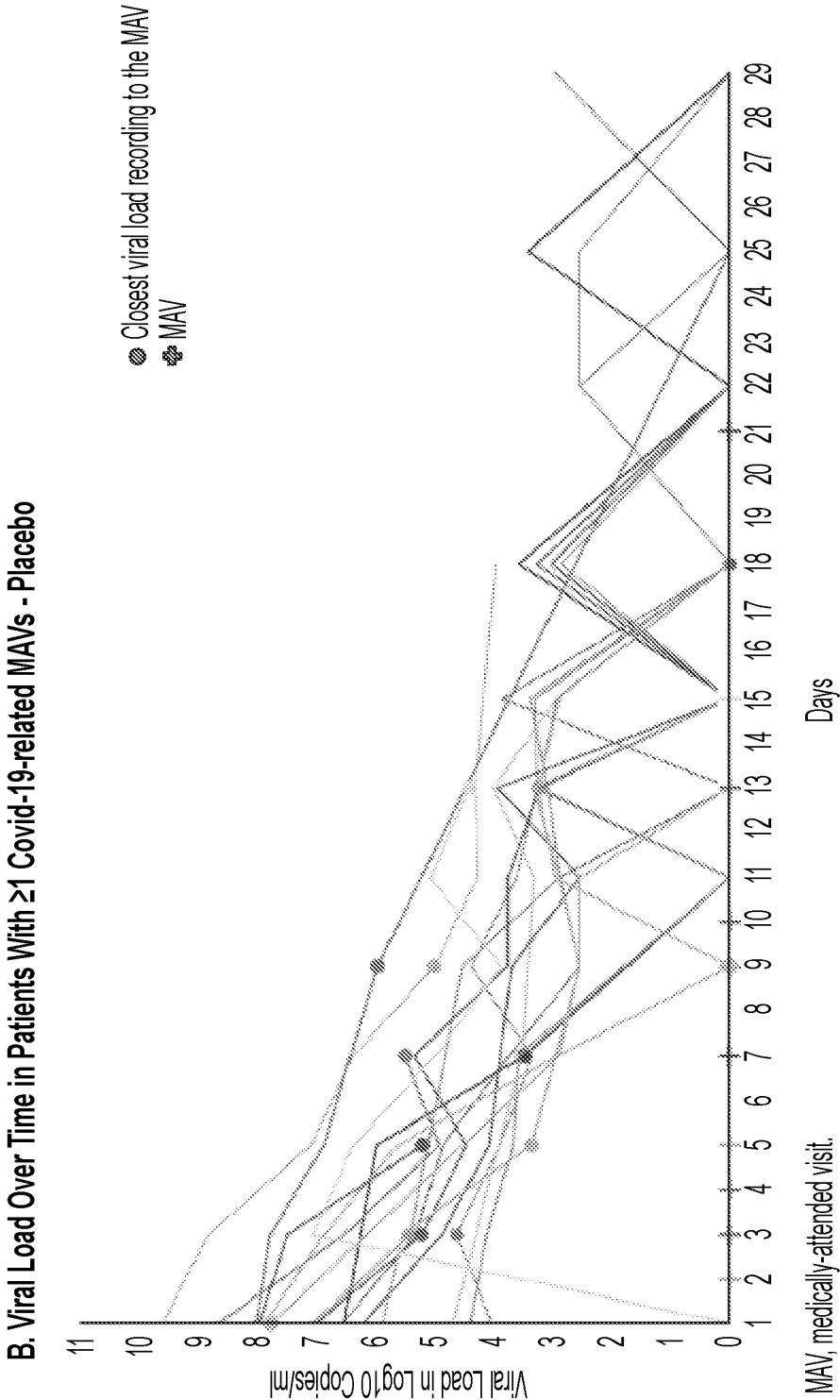


FIG. 15B

C. Viral Load Over Time in Patients With ≥ 1 Covid-19-related MAVs - REGEN-COV

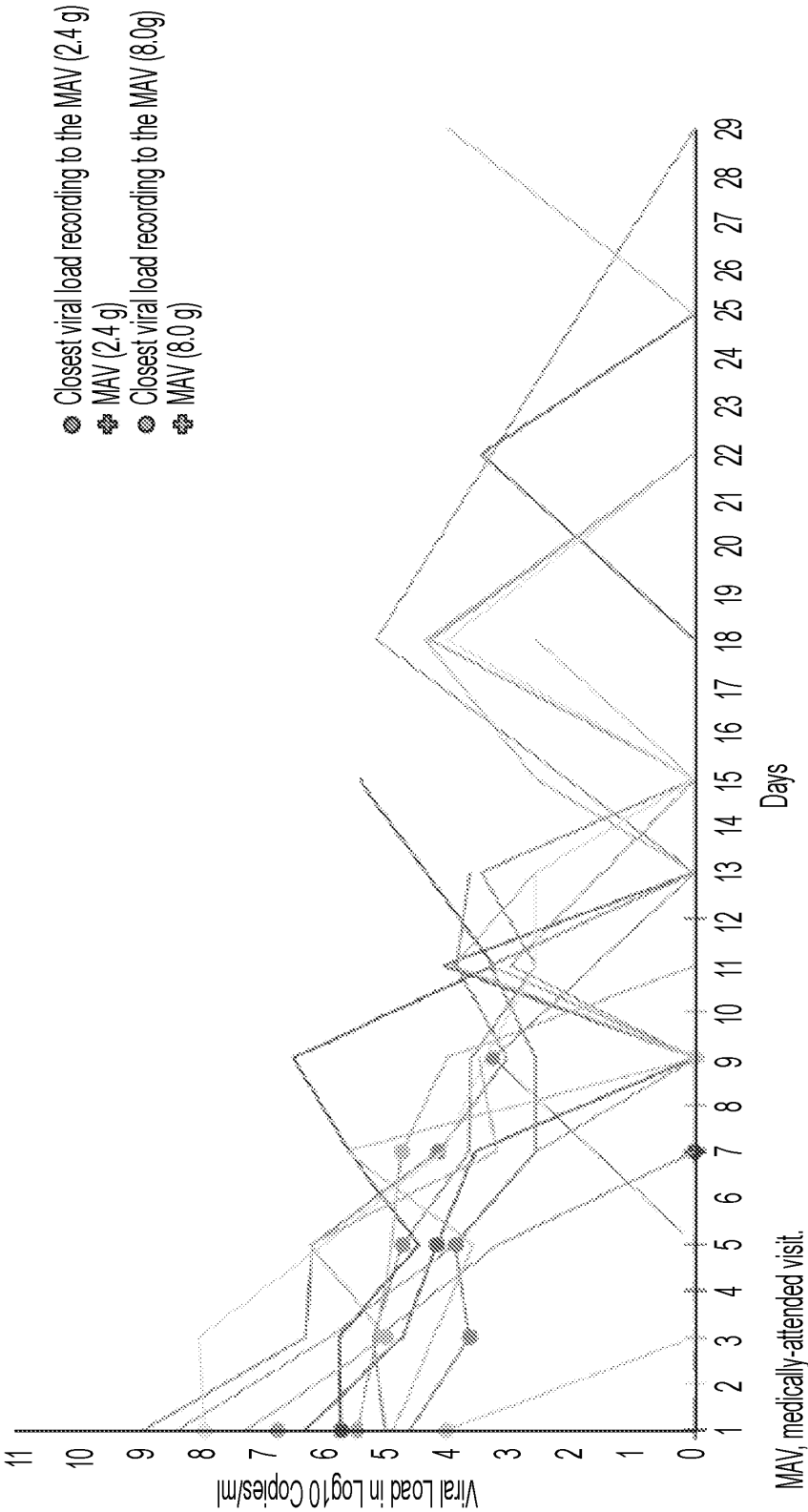


FIG. 15C

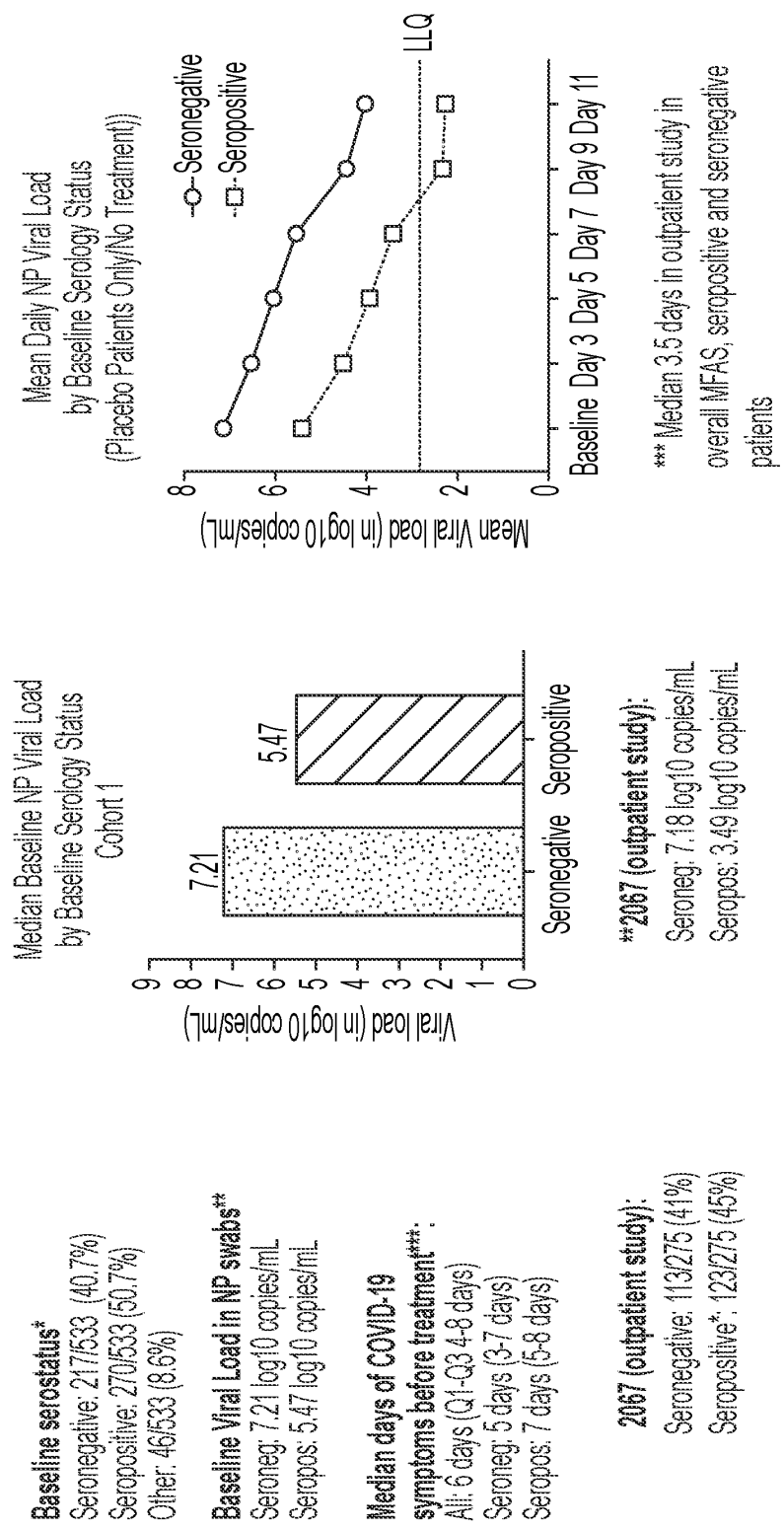


FIG. 16

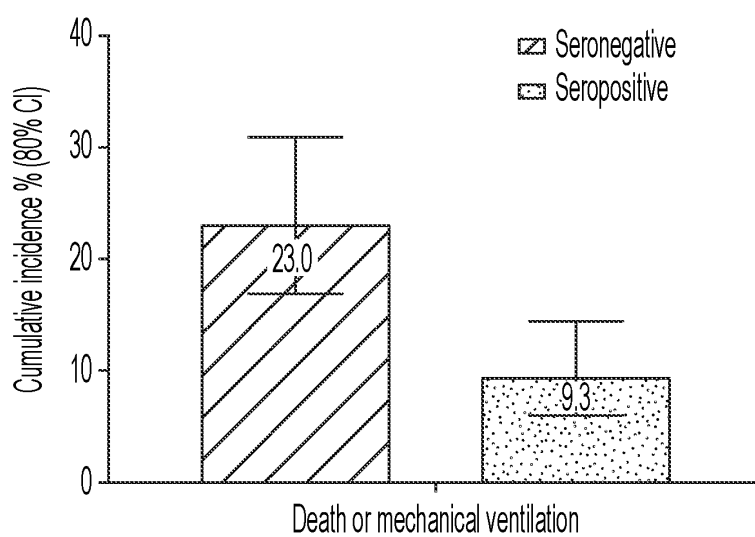


FIG. 17

By serostatus		By baseline viral load	
	Placebo-seronegative N=68		mFAS VL>10 ⁶ N=97
			mFAS VL<10 ⁶ N=80
Death or mechanical Ventilation		Death or mechanical Ventilation	
Event number	14	Event number	18
Cumulative incidence (%) (80%CI)	23.0 (16.9, 30.9)	Cumulative incidence (%) (80%CI)	20.7 (15.7, 26.9)
Death		Death	
Event number	12	Event number	15
Cumulative incidence (%) (80%CI)	20.4 (14.3, 28.7)	Cumulative incidence (%) (80%CI)	16.5 (11.9, 22.8)
Mechanical Ventilation		Mechanical Ventilation	
Event number	9	Event number	9
Cumulative incidence (%) (80%CI)	14.5 (9.7, 21.4)	Cumulative incidence (%) (80%CI)	13.7 (9.7, 19.3)
Discharge		Discharge	
Event number	51	Event number	75
Cumulative incidence (%) (80%CI)	75.0 (67.9, 81.6)	Cumulative incidence (%) (80%CI)	77.5 (71.6, 82.9)
			91.1% (86.4%, 94.8%)

FIG. 18

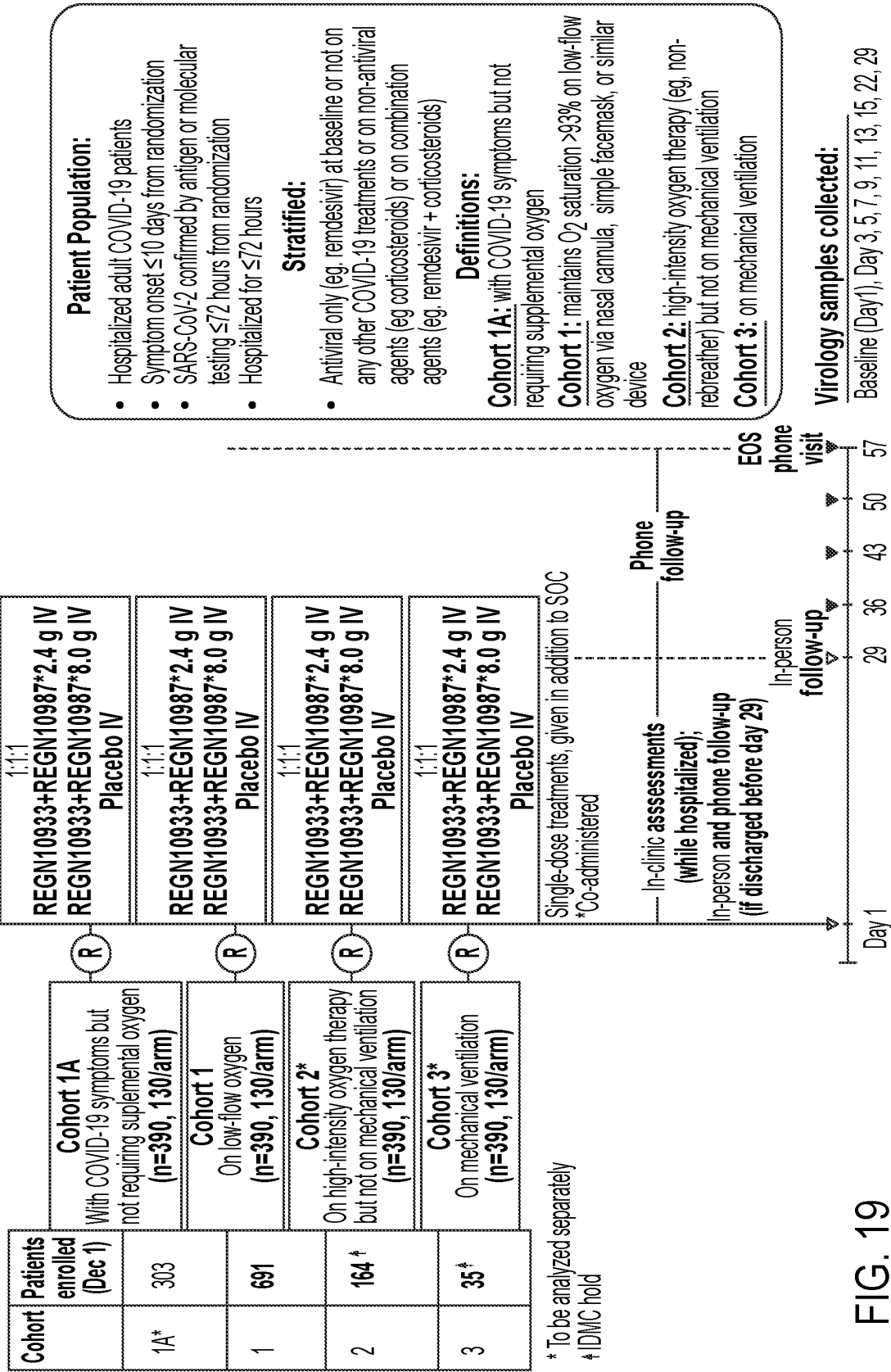


FIG. 19

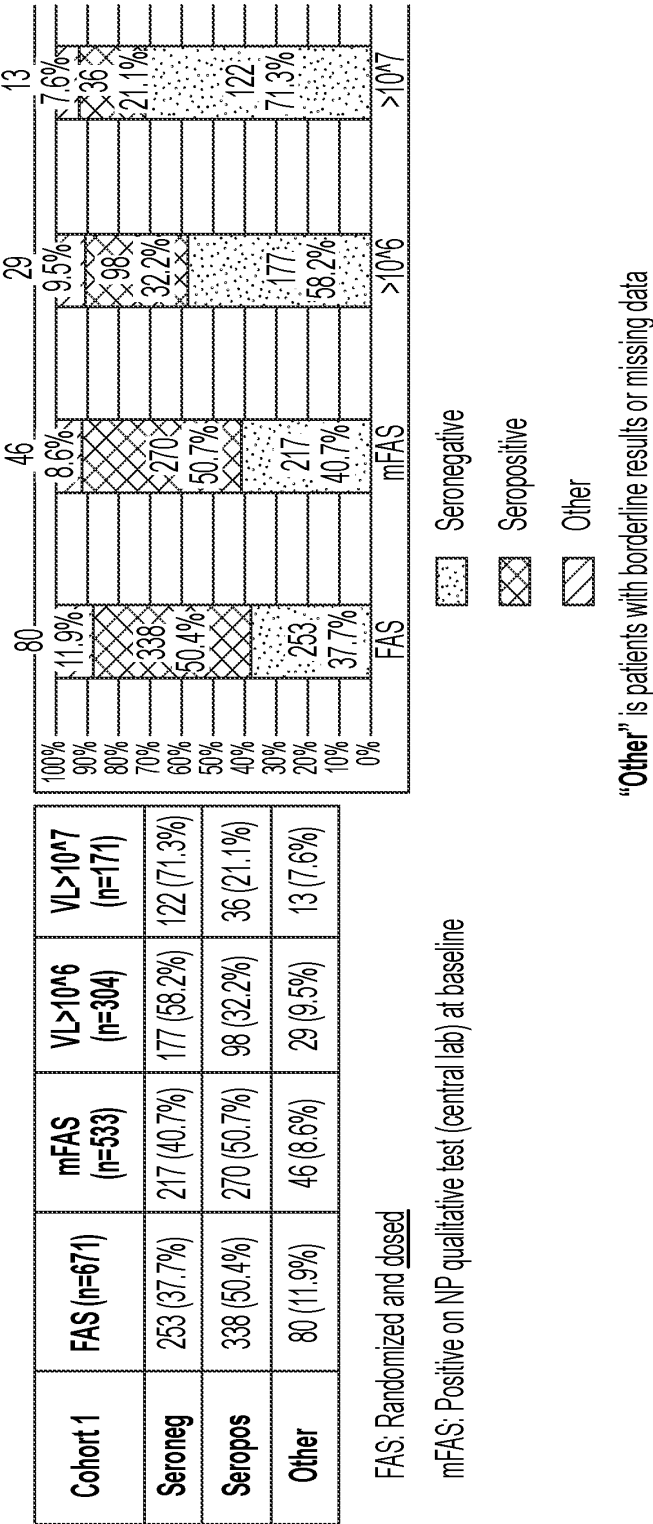


FIG. 20

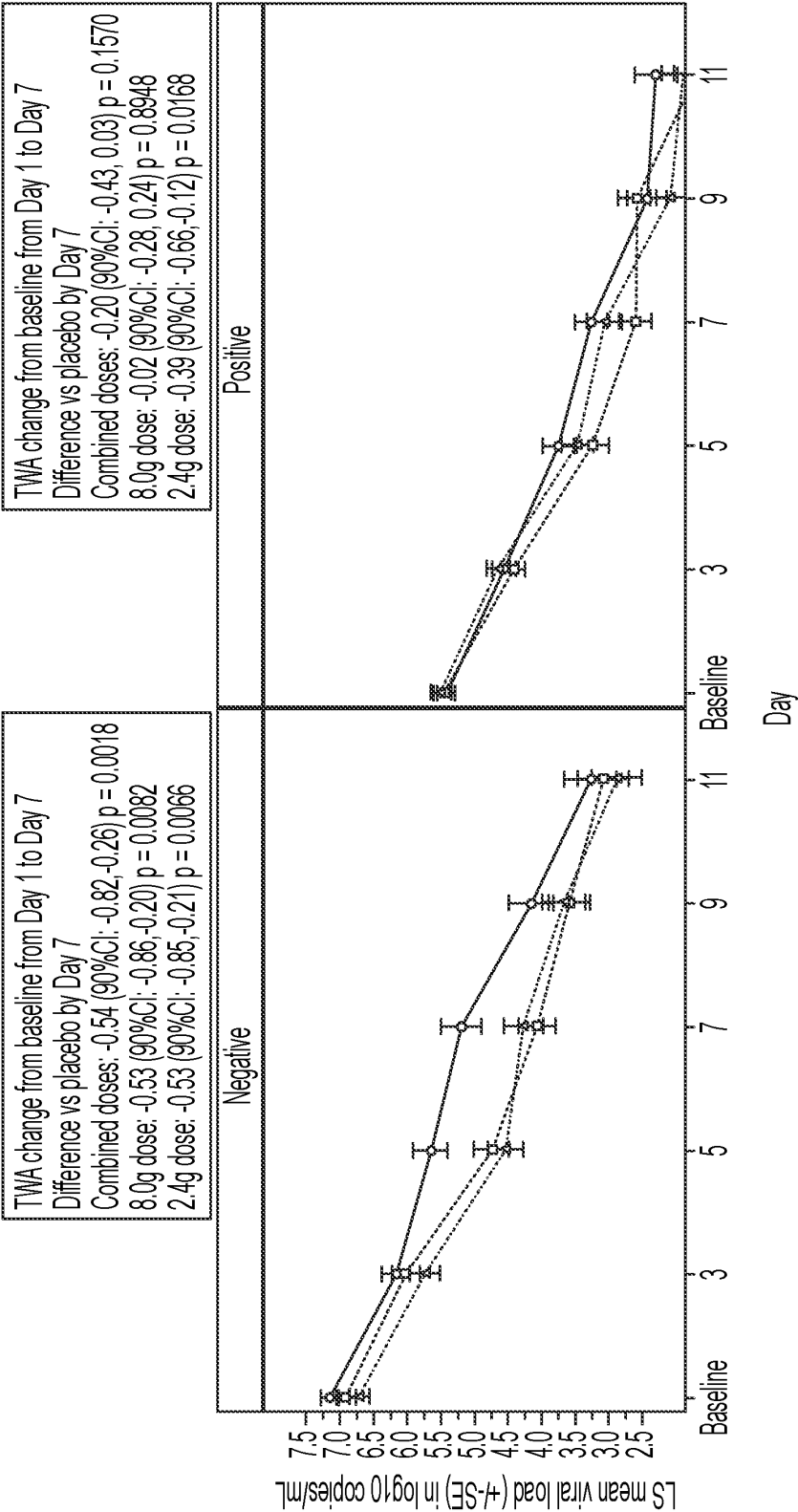


FIG. 21

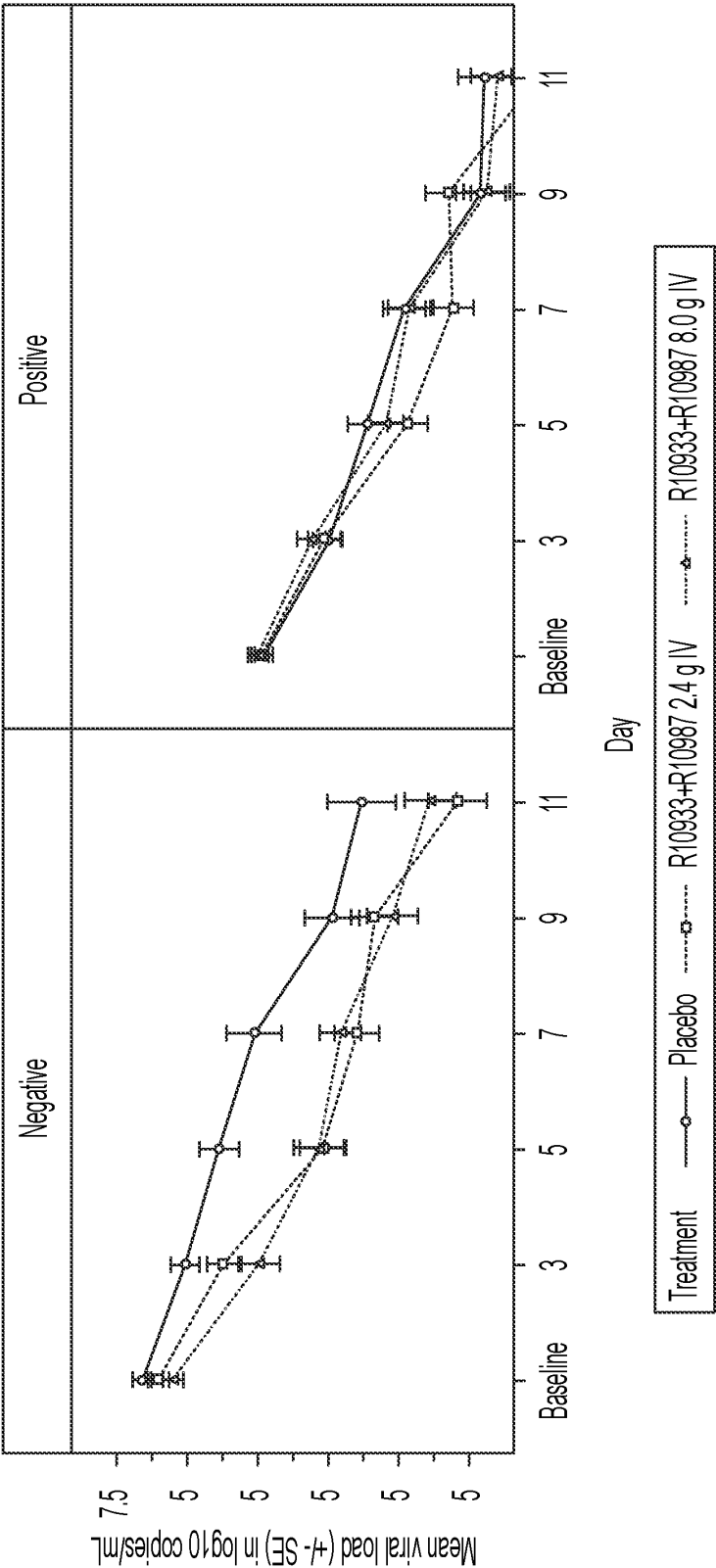


FIG. 22

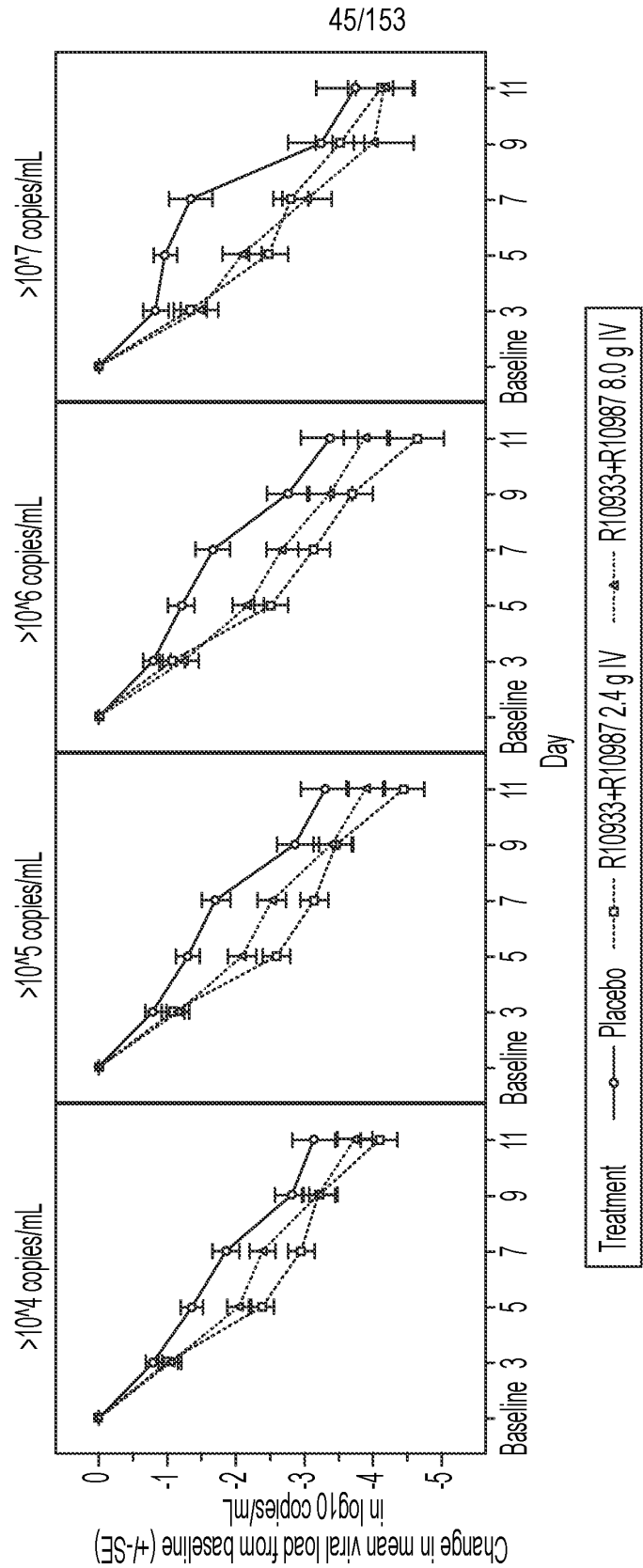


FIG. 23

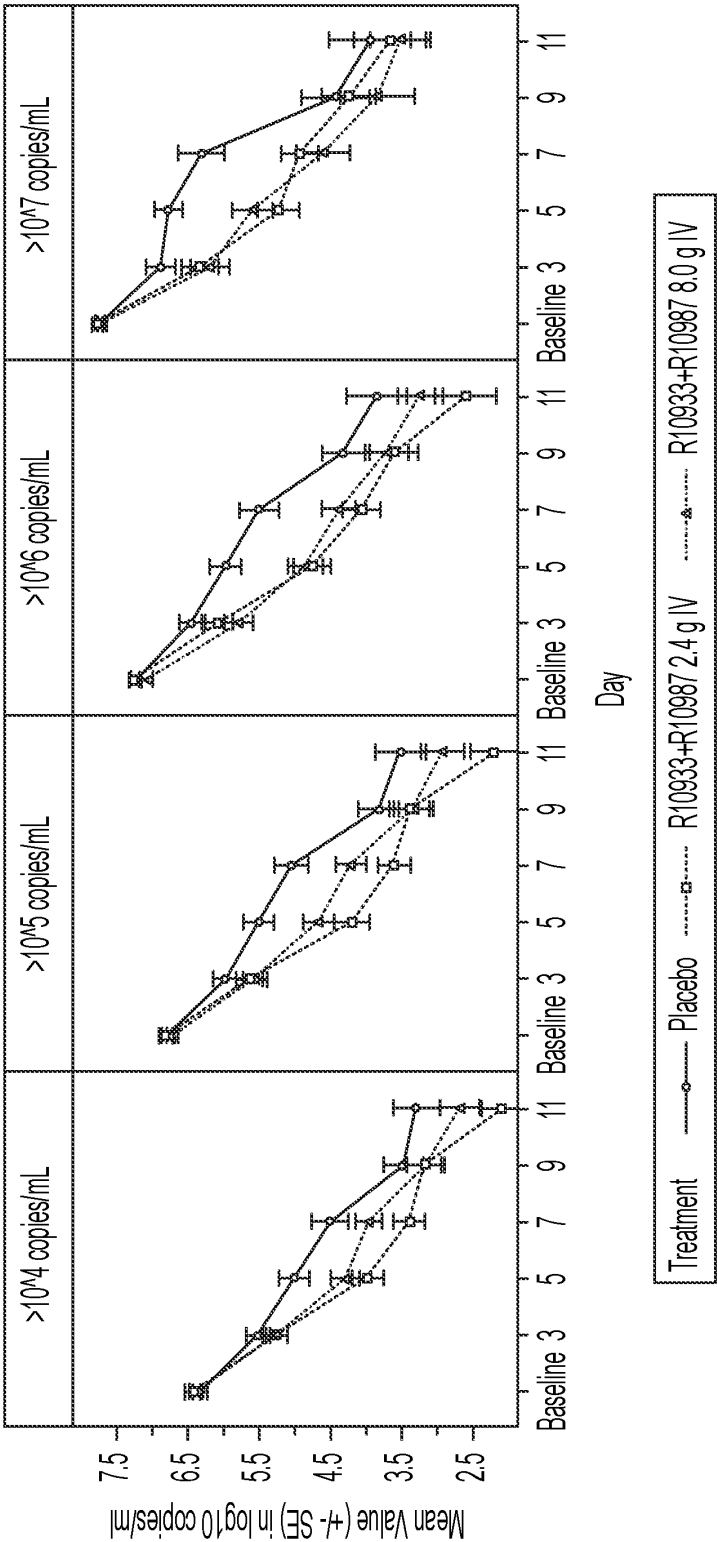
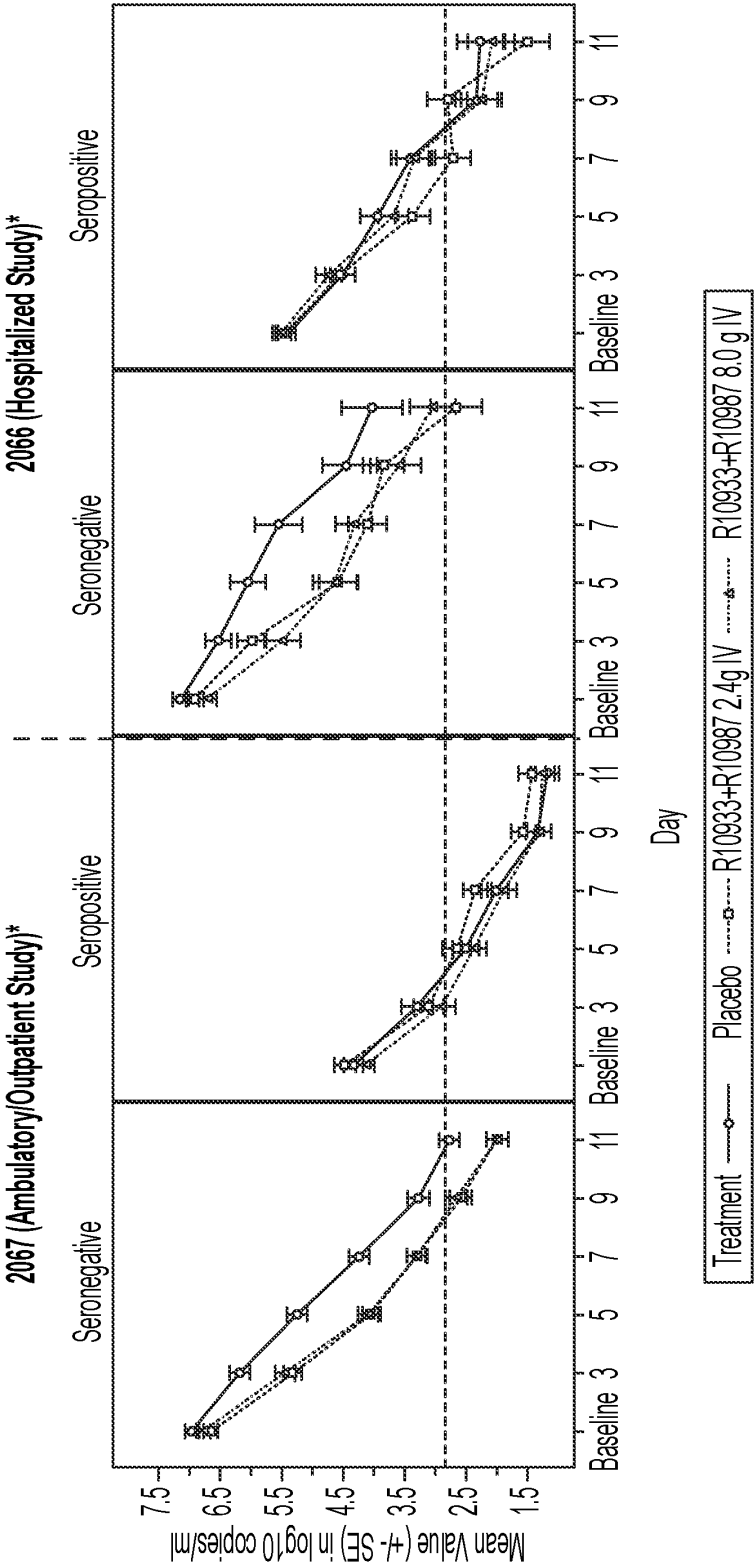
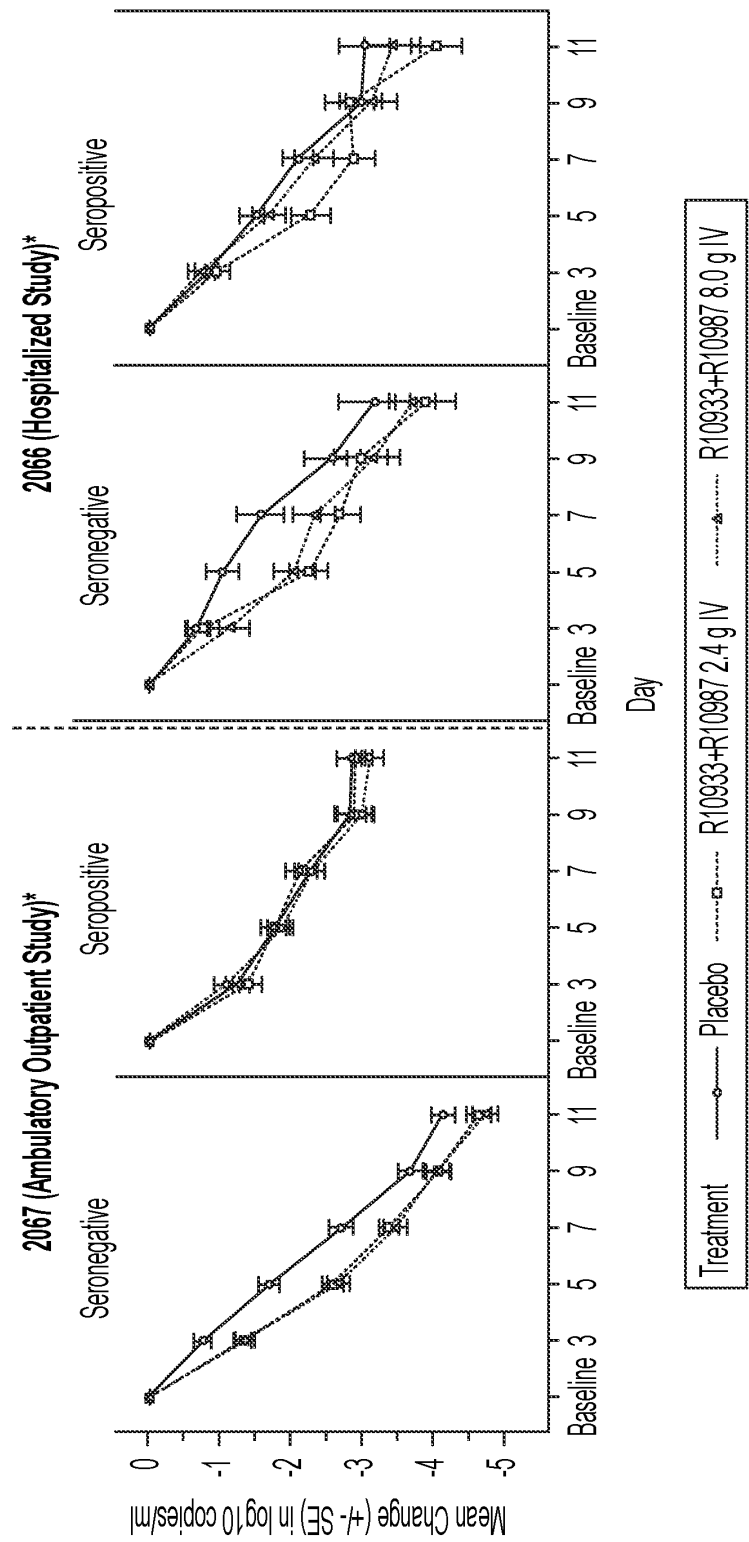


FIG. 24



*MFAS population

FIG. 25



*MFAS population

FIG. 26

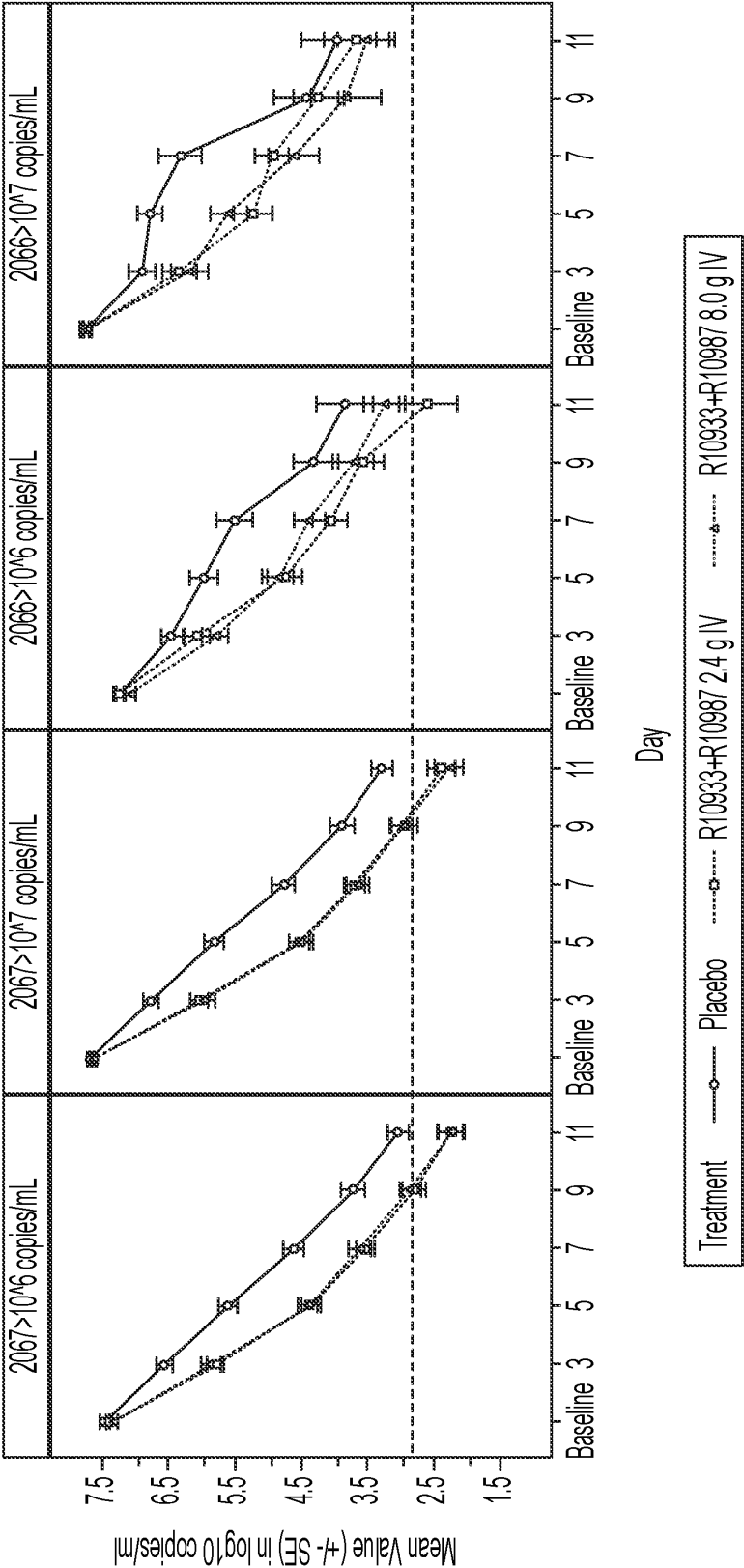


FIG. 27

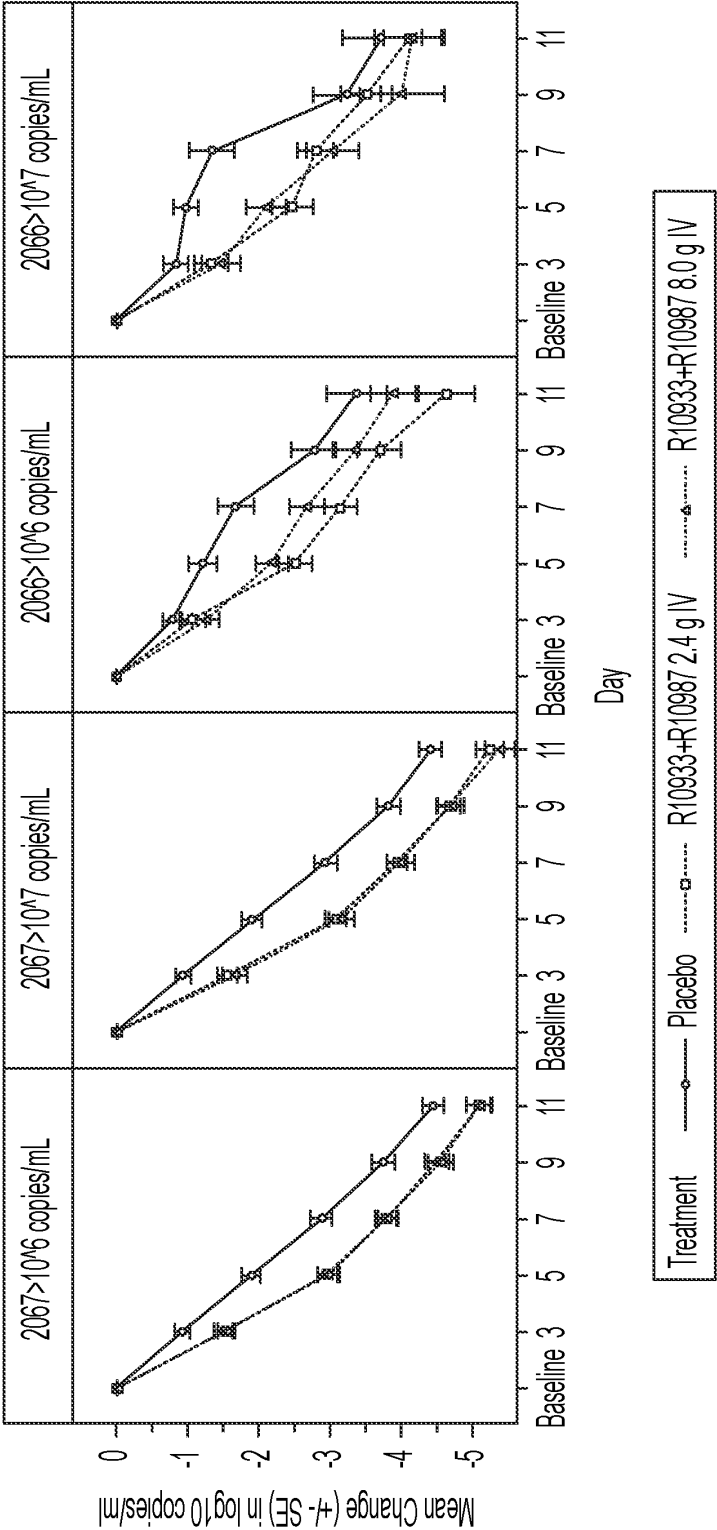


FIG. 28

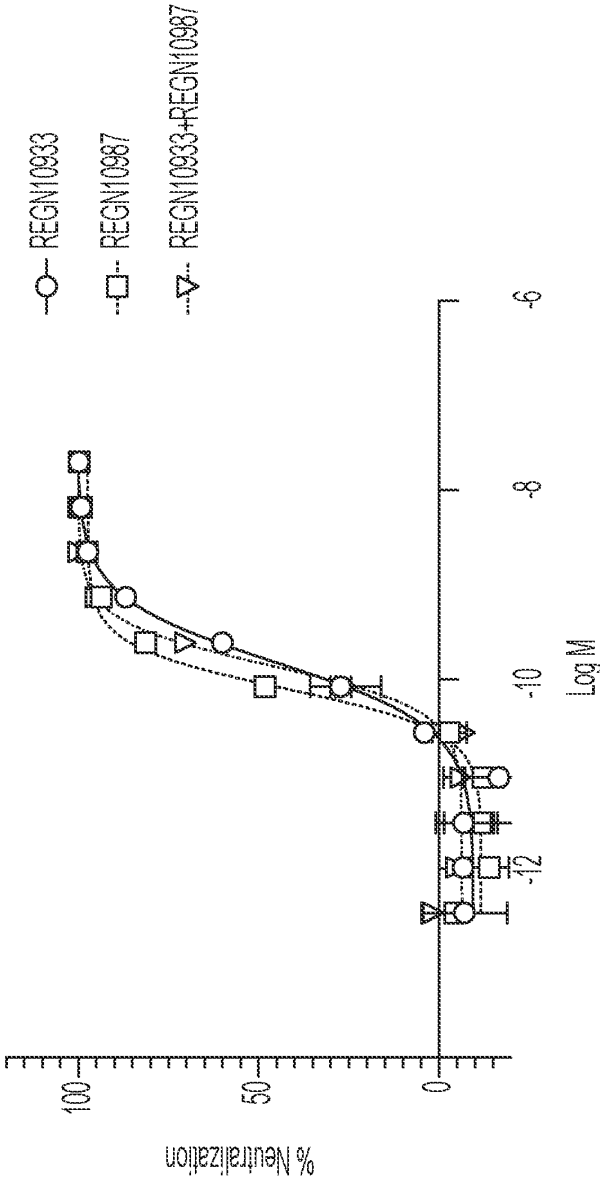


FIG. 29

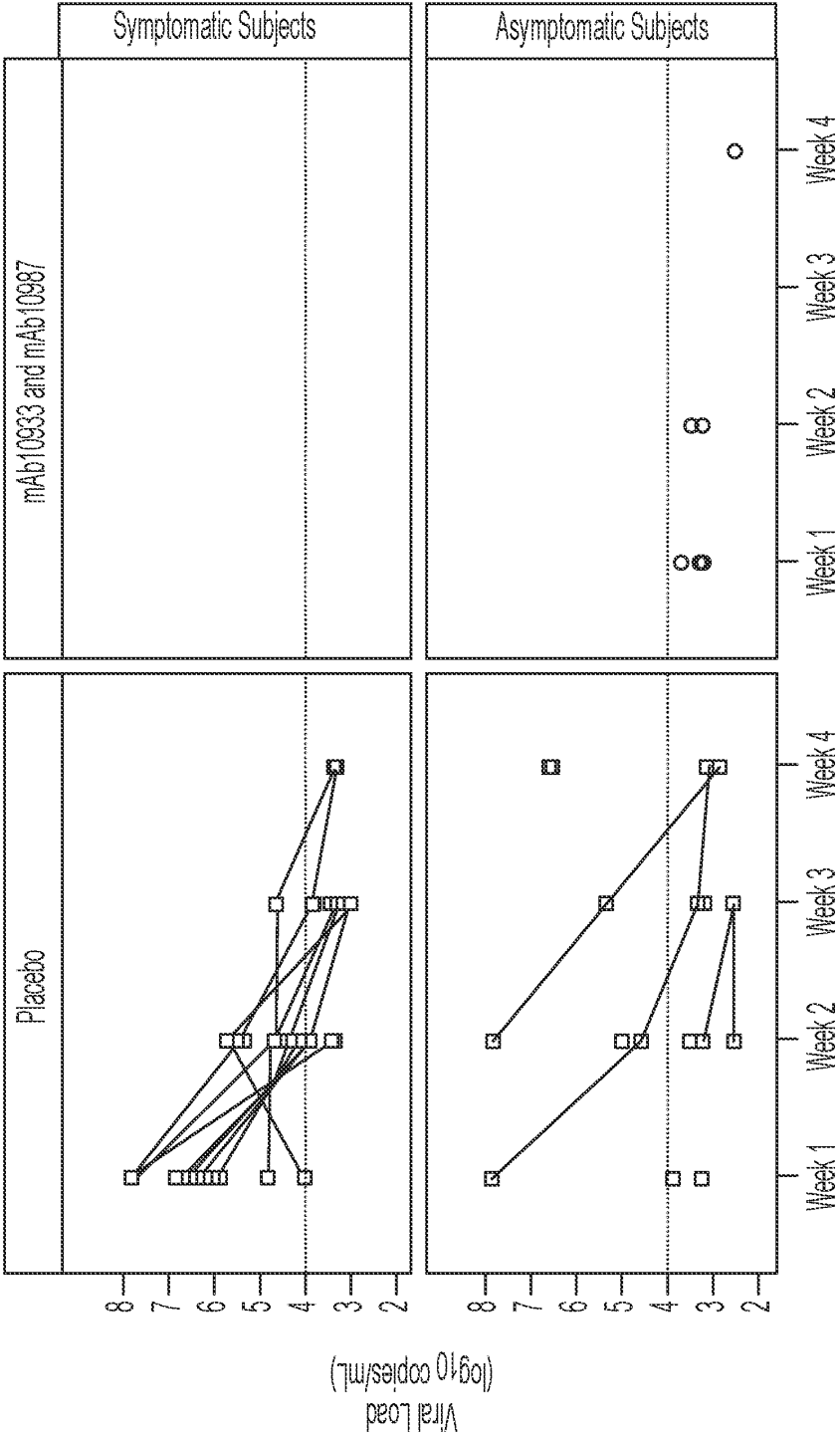
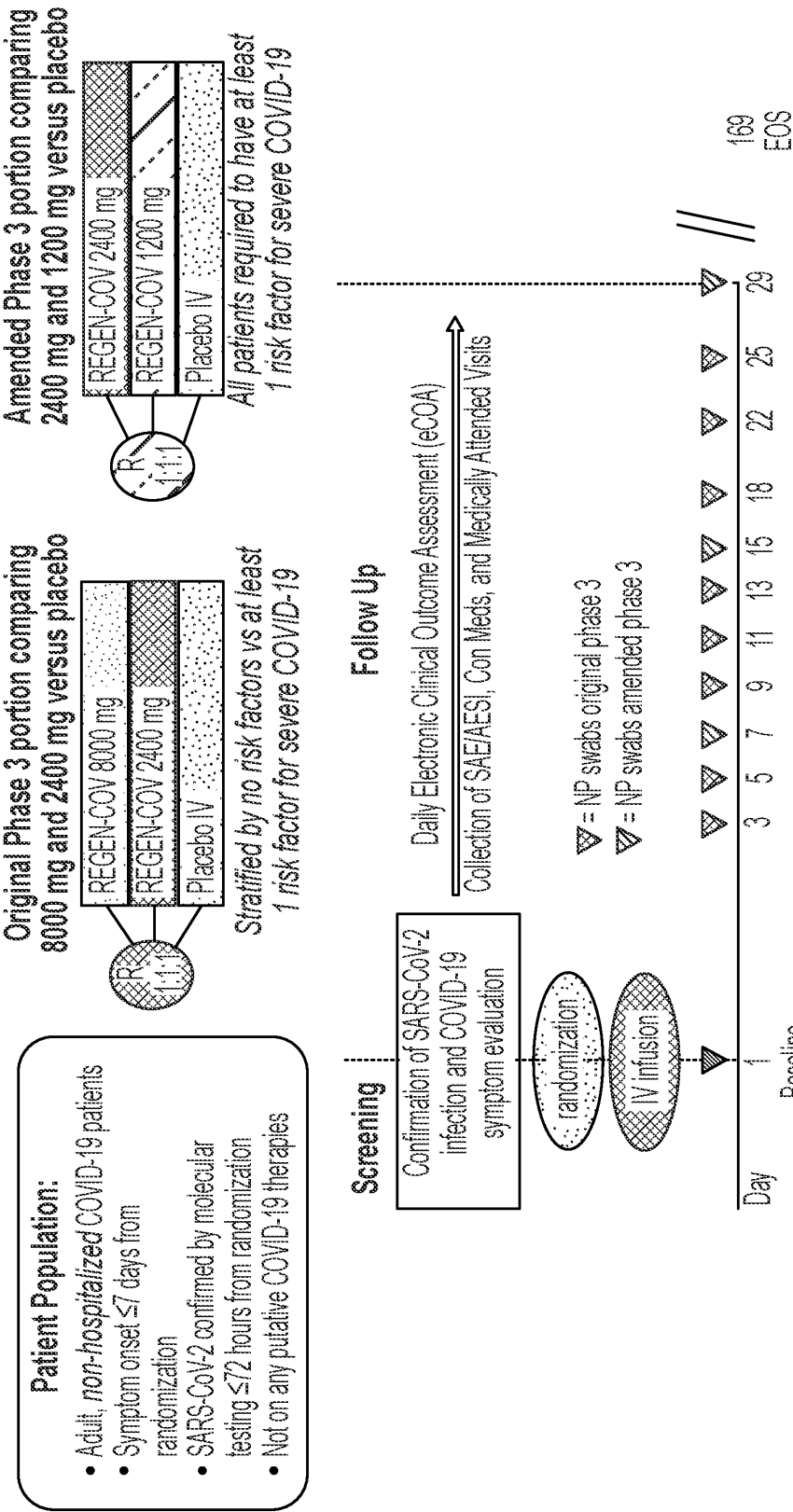


FIG. 30



FAS: all randomized patients (includes patients with and without risk factors for severe COVID-19)
mFAS: all randomized patients with a positive SARS-CoV-2 RT-qPCR test from NP swabs at randomization and ≥ 1 risk factor for severe COVID-19

FIG. 31

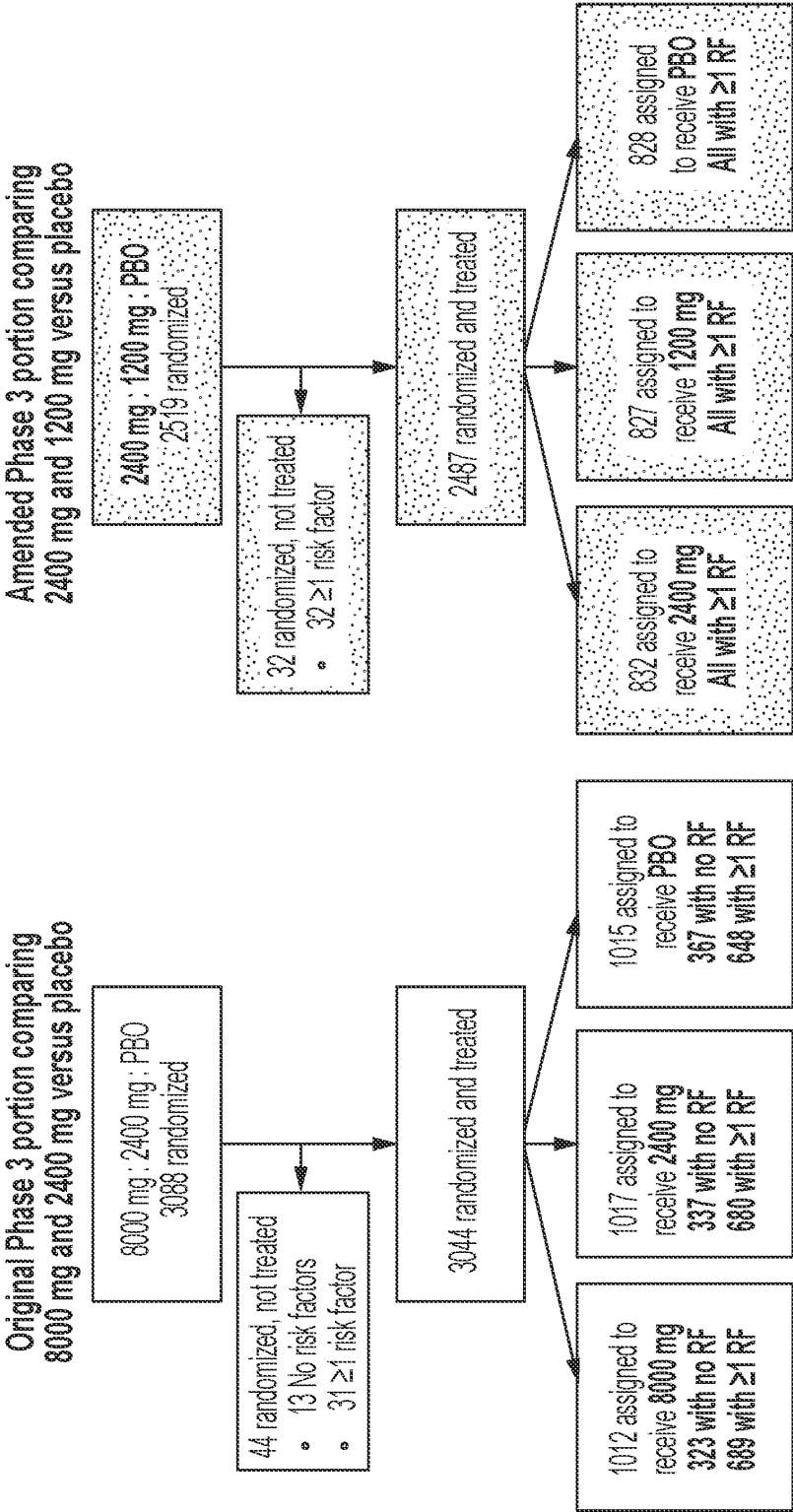


FIG. 32

Hypothesis Testing Hierarchy (all analyses in mFAS)	Comparison	Treatment effect
1. Proportion of patients with ≥ 1 COVID-19-related hospitalization or all-cause death through day 29	2400 mg vs PBO	71.3% reduction; 18/1355 (1.3%) vs 62/1341 (4.6%) 95% CI (51.7%, 82.9%); $p < 0.0001$
2. Proportion of patients with ≥ 1 COVID-19-related hospitalization or all-cause death through day 29	1200 mg vs PBO	70.4% reduction; 7/736 (1.0%) vs 24/748 (3.2%) 95% CI (31.6%, 87.1%); $p = 0.0024$
3. Proportion of patients with ≥ 1 COVID-19-related hospitalization or all-cause death through day 29 in patients with baseline viral load $>10^6$ copies/mL	2400 mg vs PBO	77.6% reduction; 13/924 (1.4%) vs 55/876 (6.3%) 95% CI (59.3%, 87.7%); $p < 0.0001$
4. Proportion of patients with ≥ 1 COVID-19-related hospitalization or all-cause death through day 29 in patients who are seronegative at baseline	2400 mg vs PBO	75.8% reduction; 12/940 (1.3%) vs 49/930 (5.3%) 95% CI (54.7%, 87.0%); $p < 0.0001$
5. Proportion of patients with ≥ 1 COVID-19-related hospitalization or all-cause death through day 29 in patients with baseline viral load $>10^6$ copies/mL	1200 mg vs PBO	70.7% reduction; 6/482 (1.2%) vs 20/471 (4.2%) 95% CI (27.6%, 88.1%); $p = 0.0045$
6. Proportion of patients with ≥ 1 COVID-19-related hospitalization or all-cause death through day 29 in patients who are seronegative at baseline	1200 mg vs PBO	82.7% reduction; 3/500 (0.6%) vs 18/519 (3.5%) 95% CI (41.6%, 94.9%); $p = 0.0014$
7. Proportion of patients with ≥ 1 COVID-19-related hospitalization or all-cause death - day 4 through day 29	2400 mg vs PBO	89.2% reduction; 5/1351 (0.4%) vs 46/1340 (3.4%) 95% CI (73.0%, 95.7%); $p < 0.0001$

FIG. 33

8. Proportion of patients with ≥ 1 COVID-19-related hospitalization or all-cause death - day 4 through day 29	1200 mg vs PBO	71.7% reduction; 5735 (0.7%) vs 18748 (2.4%)
		95% CI (24.3%, 89.4%), $p=0.0101$
9. Time to COVID-19 symptoms resolution	2400 mg vs PBO	4-day faster resolution (Median 10 vs 14 days; $p<0.0001$)
10. Time to COVID-19 symptoms resolution	1200 mg vs PBO	4-day faster resolution (Median 10 vs 14 days; $p<0.0001$)

FAS: all randomized patients (includes patients with and without risk factors for severe COVID-19)

mFAS: all randomized patients with a positive SARS-CoV-2 RT-qPCR test from NP swabs at randomization and ≥ 1 risk factor for severe COVID-19

FIG. 33 (Cont.)

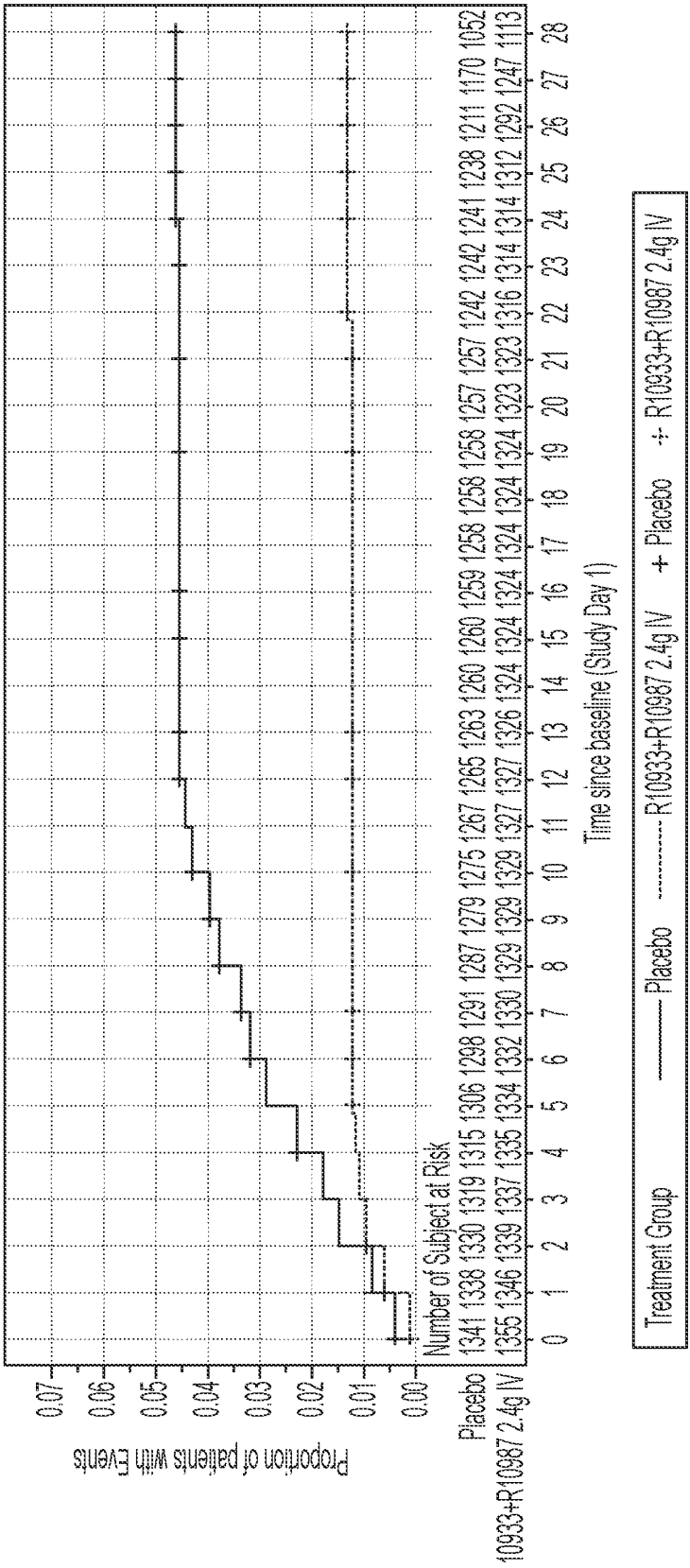
Baseline Characteristic	Phase 1/2 (high-risk) N=408	2400 mg (pooled) N=1355	PBO (2400 mg) (concurrent, pooled) N=1341	1200 mg N=736	PBO (1200 mg) (concurrent) N=748	8000 mg N=625
Mean Age (range)	48.3 (18.89)	49.3 (18.96)	47.8 (18.92)	47.6 (18.90)	47.1 (18.93)	49.7 (18.90)
Age ≥50 years (%)	48.0%	52.8%	50.6%	48.5%	47.6%	56.2%
Male (%)	46.1%	48.4%	47.2%	49.5%	47.1%	51.8%
Hispanic/Latino (%)	47.3%	34.2%	35.1%	42.4%	39.4%	28.3%
Black/AA (%)	11.3%	4.9%	4.9%	5.2%	5.1%	5.3%
BMI ≥30 kg/m ² (%)	61.8%	58.1%	57.6%	55.7%	57.1%	61.4%
≥1 Risk Factor (%)	100%	100%	100%	100%	100%	100%
Median days of symptoms prior to baseline (IQR)	3 (2-5)	3 (2-5)	3 (2-5)	3 (2-4)	3 (2-5)	3 (2-5)
Median Viral Load (log ₁₀ copies/mL)	6.48	7.01	6.95	6.92	6.85	7.00
Median Viral Load (million copies/mL)	3.04	10.3	9.0	8.4	7.1	10.1
Viral load >10 ⁶ , (%)	54.4%	68%	65%	65%	63%	68%
Seronegative, (%)	55.1%	69%	69%	68%	69%	66%
Seropositive, (%)	33.6%	24%	22%	24%	22%	26%

mFAS: all randomized patients with a positive SARS-CoV-2 RT-qPCR test from NP swabs at randomization and ≥1 risk factor for severe COVID-19

FIG. 34

**Overall mFAS Population (2400 mg vs placebo)
Study Day 1 through Study Day 29**

M. 1 Kaplan Meier Curve for Time to COVID-19-related Hospitalization or All-cause Death through Day 29 for R10933+R10987 2.4 g IV
Phase 3 Cohort 1 with ≥ 1 Risk Factor for Severe COVID-19
Modified Full Analysis Set (mFAS)



HR vs. placebo (95% CI)
2400 mg: 0.29 (0.17, 0.49); $p < 0.0001$

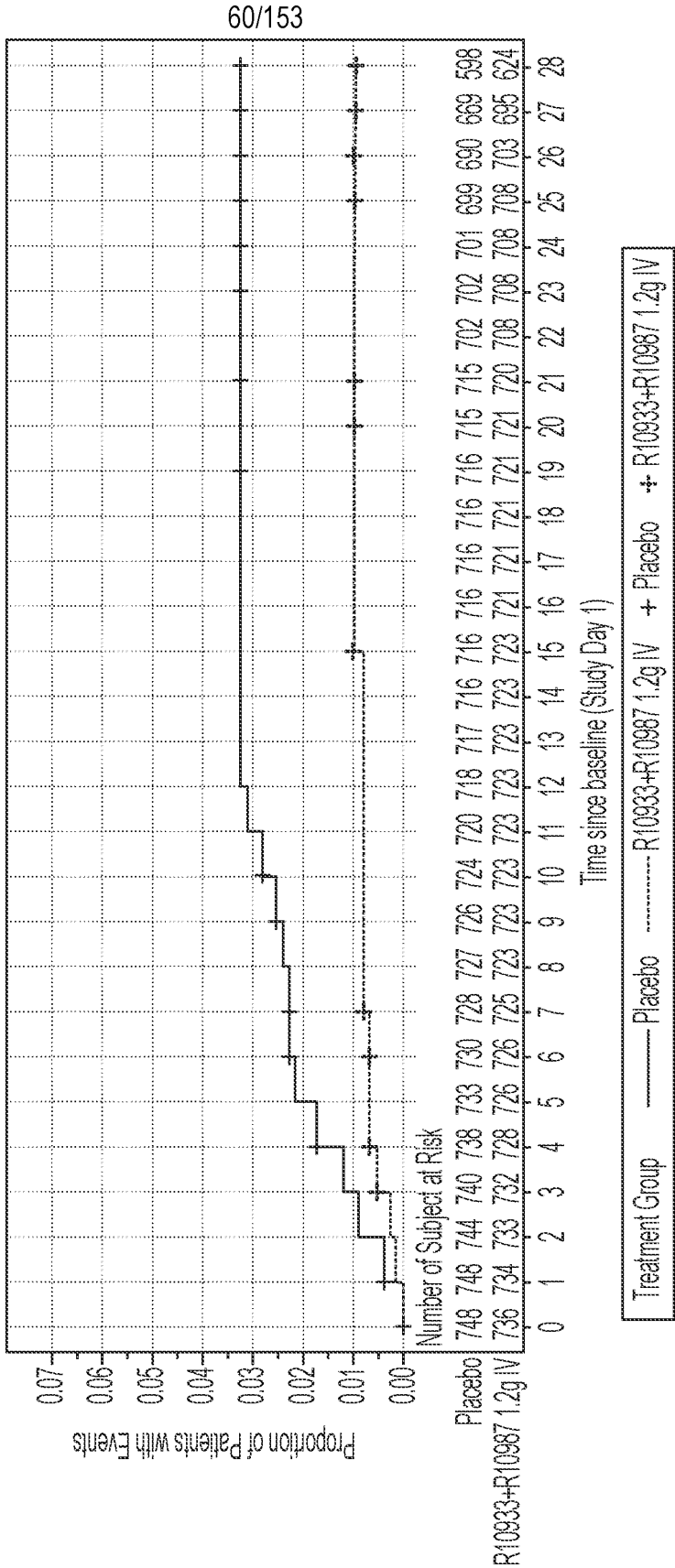
FIG. 35

Day (Study Day)	PBO			2400 mg		
	n	N	%	n	N	%
0 (1)	2	1341	0.1	6	1355	0.4
1 (2)	9	1338	0.7	12	1346	0.9
2 (3)	20	1330	1.5	13	1339	1
3 (4)	24	1319	1.8	15	1337	1.1
4 (5)	31	1315	2.3	16	1335	1.2
5 (6)	39	1306	2.9	17	1334	1.3
6 (7)	43	1298	3.2	17	1332	1.3
7 (8)	45	1291	3.4	17	1330	1.3
8 (9)	51	1287	3.8	17	1329	1.3
9 (10)	53	1279	4	17	1329	1.3
10 (11)	58	1275	4.3%	17	1327	1.3
14 (15)	61	1260	4.6	17	1324	1.3
21 (22)	61	1257	4.6	17	1323	1.3
28 (29)	62	1052	4.6	18	1113	1.3

Symbols represent censoring due to ongoing,
early termination, or study completion

FIG. 35 (Cont.)

Overall mFAS Population (1200 mg vs placebo)
Study Day 1 through Study Day 29
MP6a Kaplan Meier Curve for Time to COVID-19-related Hospitalization or All-cause Death through Day 29 for R10933+R10987 1.2g IV
Phase 3 Cohort 1 with >= 1 Risk Factor for Severe COVID-19 post PA6
Modified Full Analysis Set (mFAS)



HR vs. placebo (95% CI)
1200 mg: 0.29 (0.13, 0.68); p = 0.0014

FIG. 36

Day (Study Day)	PBO			1200 mg		
	n	N	%	n	N	%
0 (1)	0	748	0	0	736	0
1 (2)	3	748	0.4	1	734	0.1
2 (3)	7	744	0.9	2	733	0.3
3 (4)	9	740	1.2	4	732	0.5
4 (5)	13	738	1.7	5	728	0.7
5 (6)	16	733	2.1	5	726	0.7
6 (7)	17	730	2.3	5	726	0.7
7 (8)	17	728	2.3	6	725	0.8
8 (9)	18	727	2.4	6	723	0.8
9 (10)	19	726	2.5	6	723	0.8
10 (11)	21	724	2.8	6	723	0.8
14 (15)	24	716	3.2	6	723	0.8
21 (22)	24	715	3.2	7	720	1
28 (29)	24	598	3.2	7	624	1

Symbols represent censoring due to ongoing,
early termination, or study completion

FIG. 36 (Cont.)

COVID-19 Related Hospitalizations or All-Cause Deaths through Day 29
in Outpatients with 1 or more Risk Factors for Severe COVID-19
Phase 3 Study COV-2067

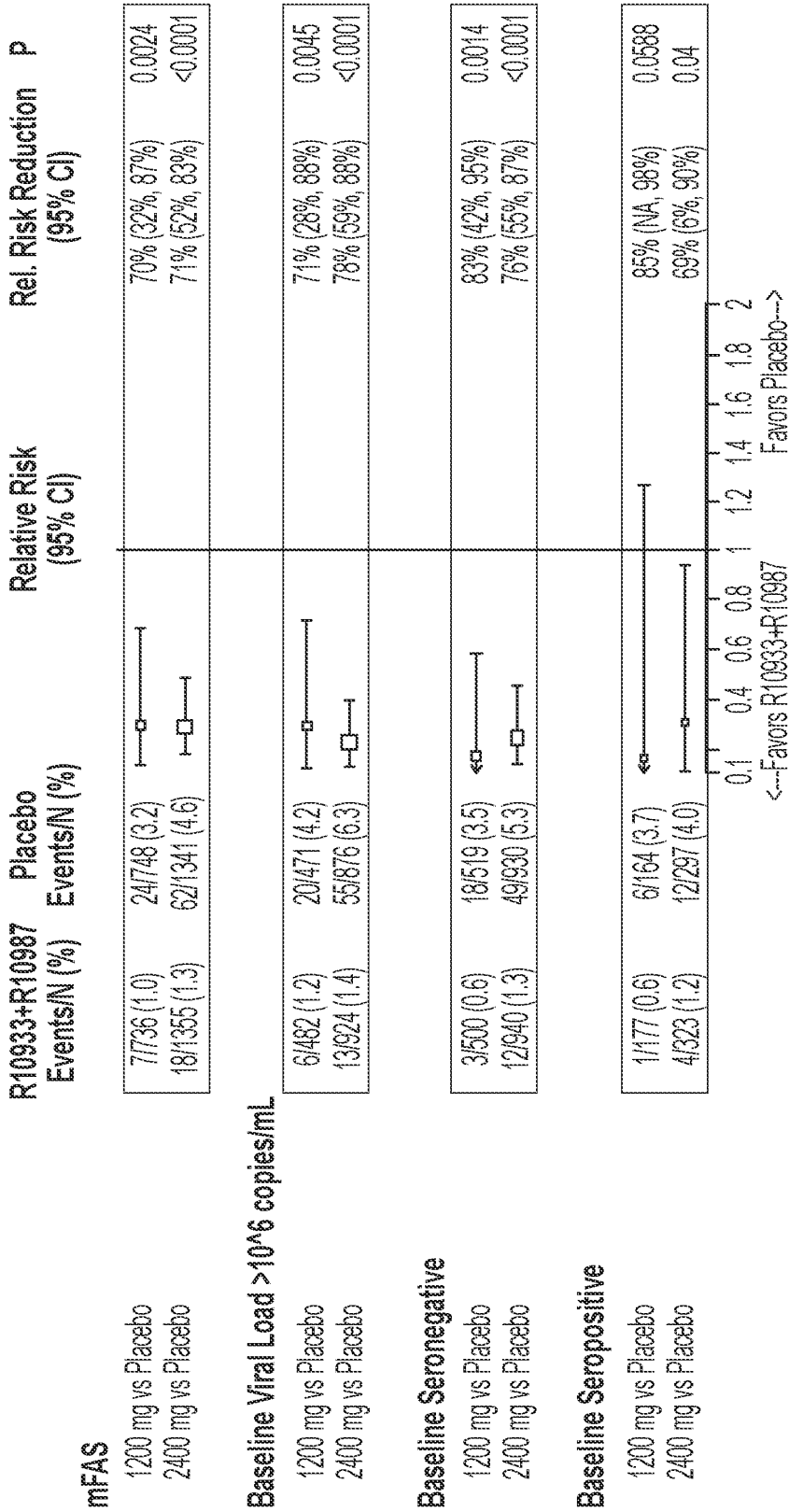


FIG. 37

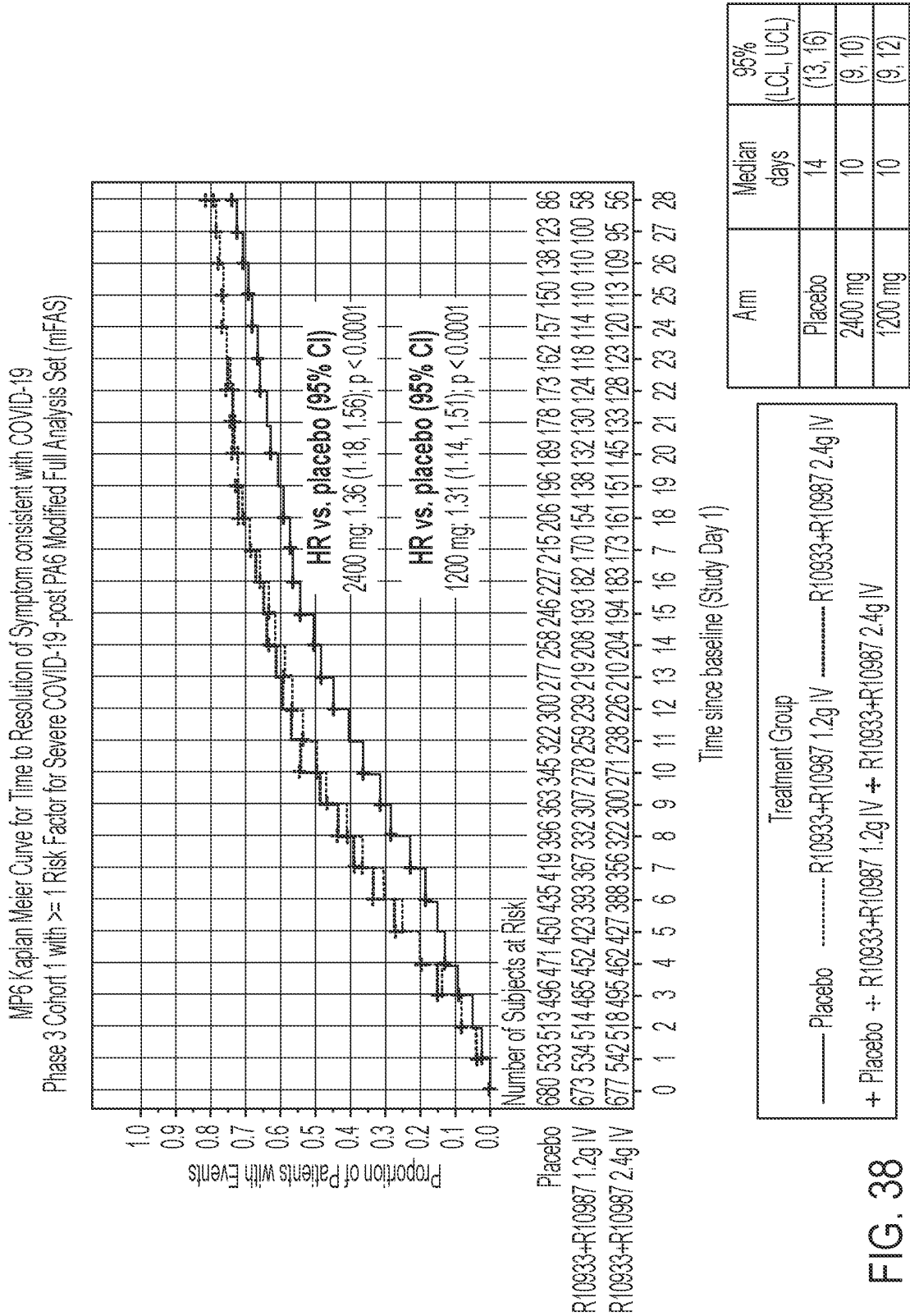


FIG. 38

64/153

**Time to Symptom Resolution
in Outpatients with 1 or more Risk Factors for Severe Covid-19
Phase 3 Study COV-2067**

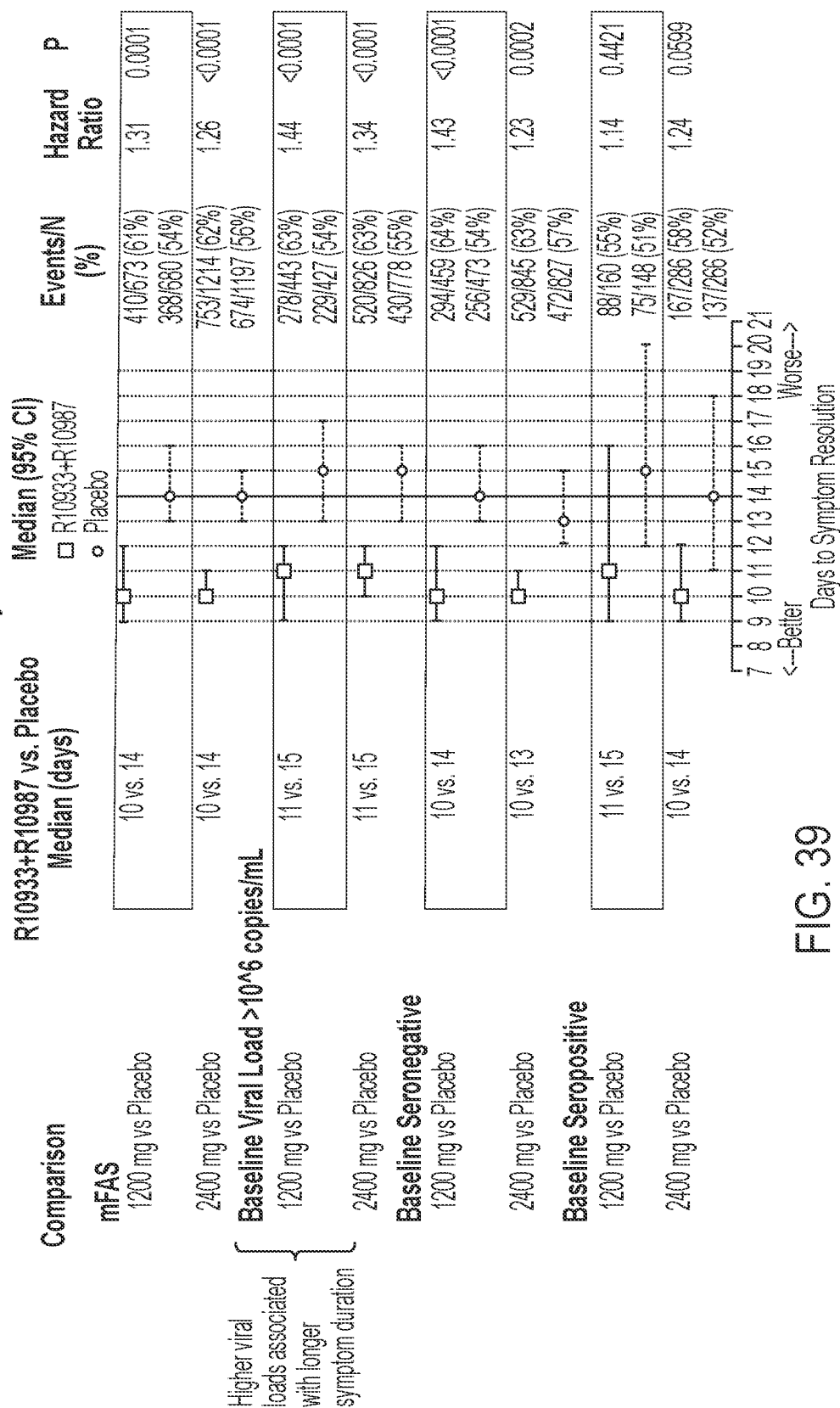


FIG. 39

	PBO (N=1843)	1200 mg IV (N=827)	2400 mg IV (N=1849)	8000 mg IV (N=1012)
AESI Infusion-related rxn ≥ Grade 2 thru Day 4	0	2 (0.2%)	1 (<0.1%)	3 (0.4%)
AESI Hypersensitivity rxn ≥ Grade 2 thru Day 29	1 (<0.1%)	0	1 (<0.1%)	0
Patients with any SAE	74 (4.0%)	9 (1.1%)	24 (1.3%)	17 (1.7%)
Deaths	5 (0.3%)	1 (0.1%)	1 (<0.1%)	0

FIG. 40

Primary System Organ Class Preferred Term	Placebo (N=1843)	1.2 g IV (N=827)	2.4 g IV (N=1849)	8.0 g IV (N=1012)	Total (N=5531)
Patients with any SAE	74 (4.0%)	9 (1.1%)	24 (1.3%)	17 (1.7%)	124 (2.2%)
Respiratory, thoracic & mediastinal disorders	22 (1.2%)	1 (0.1%)	7 (0.4%)	5 (0.5%)	35 (0.6%)
Hypoxia	6 (0.3%)	1 (0.1%)	1 (<0.1%)	1 (<0.1%)	9 (0.2%)
Dyspnea	7 (0.4%)	0	1 (<0.1%)	1 (0.1%)	9 (0.2%)
Acute respiratory failure	3 (0.2%)	0	2 (0.1%)	1 (<0.1%)	6 (0.1%)
Respiratory distress	2 (0.1%)	0	0	0	2 (<0.1%)
Infections and infestations	48 (2.6%)	5 (0.6%)	14 (0.8%)	12 (1.2%)	79 (1.4%)
COVID-19	18 (1.0%)	1 (0.1%)	5 (0.3%)	5 (0.5%)	29 (0.5%)
COVID-19 pneumonia	14 (0.8%)	2 (0.2%)	4 (0.2%)	5 (0.5%)	25 (0.5%)
Pneumonia	17 (0.9%)	2 (0.2%)	3 (0.2%)	1 (<0.1%)	23 (0.4%)
Metabolism and nutrition disorders	4 (0.2%)	0	0	0	4 (<0.1%)
Dehydration	2 (0.1%)	0	0	0	2 (<0.1%)
Hyponatremia	2 (0.1%)	0	0	0	2 (<0.1%)

FIG. 41

Primary System Organ Class Preferred Term	Placebo (N=1843)	1.2 g IV (N=827)	2.4 g IV (N=1849)	8.0 g IV (N=1012)	Total (N=5531)
Patients with any Infusion Related Rxn	0	2 (0.2%)	1 (<0.1%)	3 (0.4%)	6 (0.1%)
Infusion related reaction	0	1 (0.1%)	1 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Nausea	0	1 (0.1%)	0	1 (<0.1%)	2 (<0.1%)
Dizziness	0	1 (0.1%)	0	0	1 (<0.1%)
Headache	0	1 (0.1%)	0	0	1 (<0.1%)
Hyperhidrosis	0	0	0	1 (<0.1%)	1 (<0.1%)
Hyporesponsive to stimuli	0	0	0	1 (<0.1%)	1 (<0.1%)
Rash	0	0	0	1 (<0.1%)	1 (<0.1%)
Vomiting	0	0	0	1 (<0.1%)	1 (<0.1%)
Patients with any Hypersensitivity Rxn	1 (<0.1%)	0	1 (<0.1%)	0	2 (<0.1%)
Urticaria	1 (<0.1%)	0	1 (<0.1%)	0	2 (<0.1%)

FIG. 42

68/153

**Change from Baseline in Viral Load (log₁₀ copies/mL) at Day 7
in Outpatients with 1 or more Risk Factors for Severe COVID-19
Phase 3 Study COV-2067**

	R10933+R10987 LSMean (SE)	Placebo LSMean (SE)	Difference in LS Means (95% CI)	Difference (95% CI) P Value
mFAS				
1200 mg vs Placebo (n=1484)	-3.35 (0.09)	-2.64 (0.09)		-0.71 (-0.90, -0.53) <0.0001
2400 mg vs Placebo (n=2696)	-3.32 (0.09)	-2.47 (0.09)		-0.86 (-1.00, -0.72) <0.0001
Baseline Viral Load >10⁶ copies/mL				
1200 mg vs Placebo (n=953)	-4.09 (0.12)	-3.07 (0.12)		-1.01 (-1.24, -0.79) <0.0001
2400 mg vs Placebo (n=1800)	-3.91 (0.12)	-2.87 (0.12)		-1.04 (-1.20, -0.87) <0.0001
Baseline Seronegative				
1200 mg vs Placebo (n=963)	-3.56 (0.11)	-2.70 (0.11)		-0.86 (-1.09, -0.64) <0.0001
2400 mg vs Placebo (n=1870)	-3.58 (0.11)	-2.55 (0.11)		-1.04 (-1.20, -0.87) <0.0001
Baseline Seropositive				
1200 mg vs Placebo (n=341)	-2.53 (0.15)	-2.36 (0.16)		-0.16 (-0.53, 0.20) 0.3799
2400 mg vs Placebo (n=620)	-2.36 (0.18)	-1.94 (0.19)		-0.43 (-0.70, -0.15) 0.0027

-1.5 -1.25 -1 -0.75 -0.5 -0.25 0 0.25
 <---Favors R10933+R10987 Favors Placebo-->

FIG. 43

Analysis Set		Pre PA6 Placebo	Pre PA6 2400 mg	Pre PA6 8000 mg	PA6 or later Placebo	PA6 or later 1200 mg	PA6 or later 2400 mg
mFAS	N	N=589	N=617	N=625	N=744	N=734	N=736
	Baseline, mean (SD)	6.70 (1.664)	6.62 (1.630)	6.64 (1.671)	6.63 (1.823)	6.73 (1.863)	6.80 (1.765)
	MEAN (SD) Day 7	3.87 (2.077)	2.95 (1.858)	2.97 (1.859)	3.48 (2.163)	2.85 (1.854)	2.70 (1.916)
	Mean change from baseline at D7	-2.84 (1.921)	-3.65 (1.833)	-3.67 (1.901)	-3.14 (1.964)	-3.90 (2.027)	-4.09 (2.002)
With hospitalization /deaths	N	N=37	N=7	N=13	N=24	N=7	N=11
	Baseline, mean (SD)	7.56 (1.225)	6.72 (1.044)	6.15 (1.735)	7.50 (1.120)	7.62 (1.425)	6.22 (1.976)
	MEAN (SD) Day 7	5.54 (1.462)	2.66 (1.808)	3.10 (2.324)	5.03 (1.106)	3.70 (2.493)	3.14 (2.262)
	Mean change from baseline at D7	-2.12 (1.348)	-4.08 (2.294)	-2.25 (1.907)	-2.69 (1.421)	-4.29 (2.136)	-2.28 (3.379)
Without hospitalization /deaths	N	N=552	N=610	N=612	N=720	N=727	N=725
	Baseline, mean (SD)	6.65 (1.674)	6.62 (1.636)	6.65 (1.669)	6.60 (1.836)	6.72 (1.865)	6.81 (1.762)
	MEAN (SD) Day 7	3.80 (2.071)	2.95 (1.860)	2.97 (1.853)	3.45 (2.168)	2.84 (1.850)	2.70 (1.916)
	Mean change from baseline at D7	-2.86 (1.936)	-3.65 (1.832)	-3.68 (1.897)	-3.14 (1.972)	-3.89 (2.028)	-4.10 (1.991)

FIG. 44

	Pooled Placebo (N=77)	REGEN-COV 300 mg IV (N=80)	REGEN-COV 600 mg IV (N=68)	REGEN-COV 1200 mg IV (N=72)	REGEN-COV 2400 mg IV (N=62)	Total (N=359)
Age (years) Mean (SD)	35.1 (9.97)	33.8 (8.90)	33.9 (9.16)	34.1 (10.51)	36.3 (9.16)	34.6 (9.55)
Sex, n (%)						
Male	31 (40.3%)	33 (41.3%)	39 (57.4%)	29 (40.3%)	28 (45.2%)	160 (44.6%)
Female	46 (59.7%)	47 (58.8%)	29 (42.6%)	43 (59.7%)	34 (54.8%)	199 (55.4%)
Ethnicity, n (%)						
Hispanic or Latino	27 (35.1%)	28 (35%)	16 (23.5%)	26 (36.1%)	24 (38.7)	121 (33.7%)
Not Hispanic or Latino	50 (64.9%)	52 (65%)	52 (76.5%)	43 (59.7)	38 (61.3%)	235 (65.5%)
Not Reported	0	0	0	3 (4.2%)	0	3 (0.8%)
Weight (kg) Mean (SD)	74.04 (16.05)	73.12 (14.01)	73.12 (13.45)	73.12 (13.54)	73.21 (12.33)	73.33 (13.94)

FIG. 45

	Pooled Placebo (N=77)	REGEN-COV 600 mg SC (N=75)	REGEN-COV 1200 mg SC (N=73)	Total (N=225)
Age (years) Mean (SD)	35.1 (9.97)	33.5 (9.18)	33.5 (10.88)	34.1 (10.00)
Sex, n (%)	31 (40.3%)	36 (48.0%)	35 (47.9%)	102 (45.3%)
	46 (59.7%)	39 (52.0%)	38 (52.1%)	123 (54.7%)
Ethnicity, n (%)	27 (35.1%)	30 (40.0%)	21 (28.8%)	78 (34.7%)
	50 (64.9%)	44 (58.7%)	50 (68.5%)	144 (64.0%)
	0	1 (1.3%)	2 (2.7%)	3 (1.3%)
Weight (kg) Mean (SD)	74.04 (16.05)	72.77 (12.48)	74.51 (13.48)	73.77 (14.06)

FIG. 46

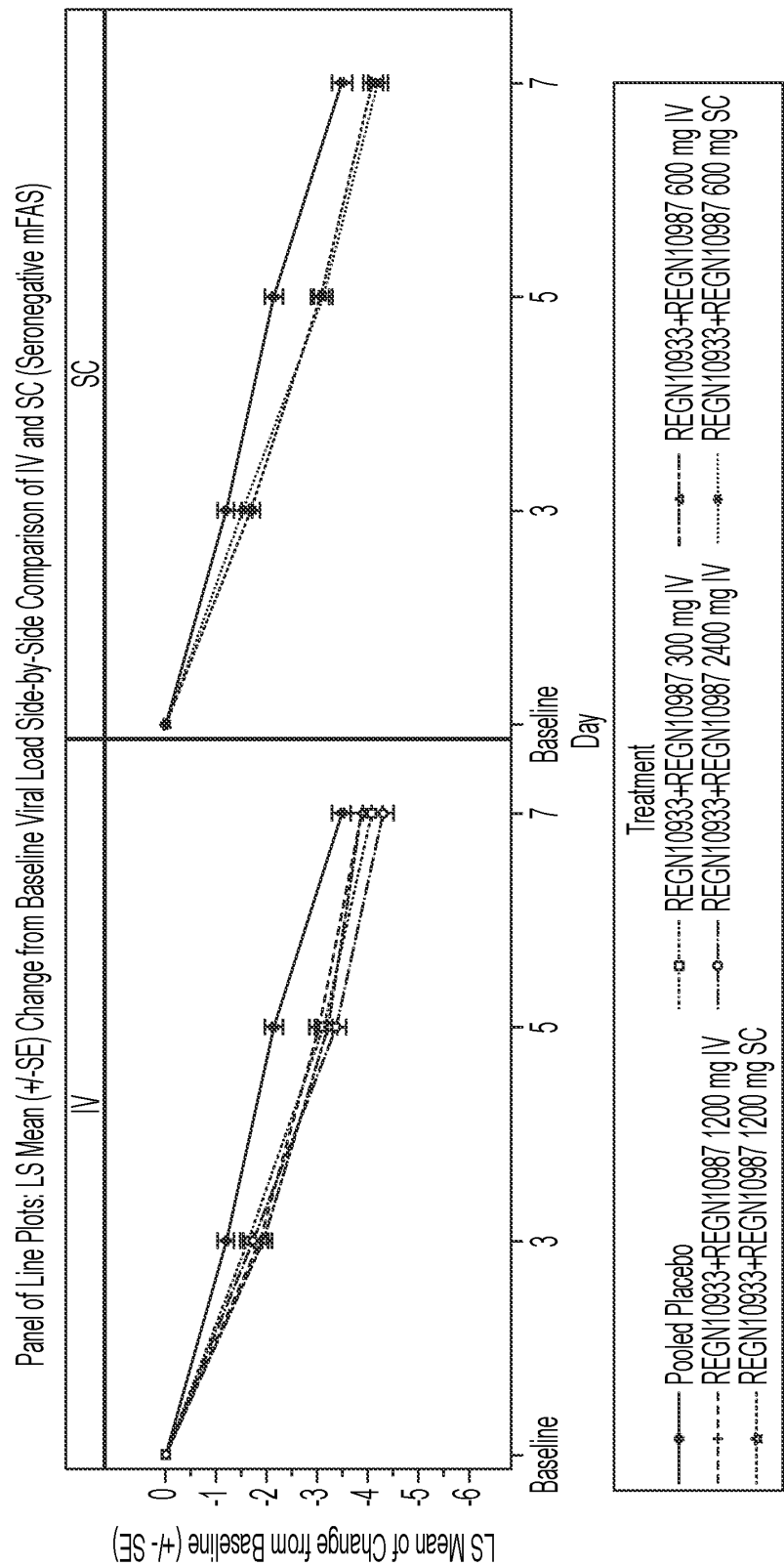


FIG. 47

73/153

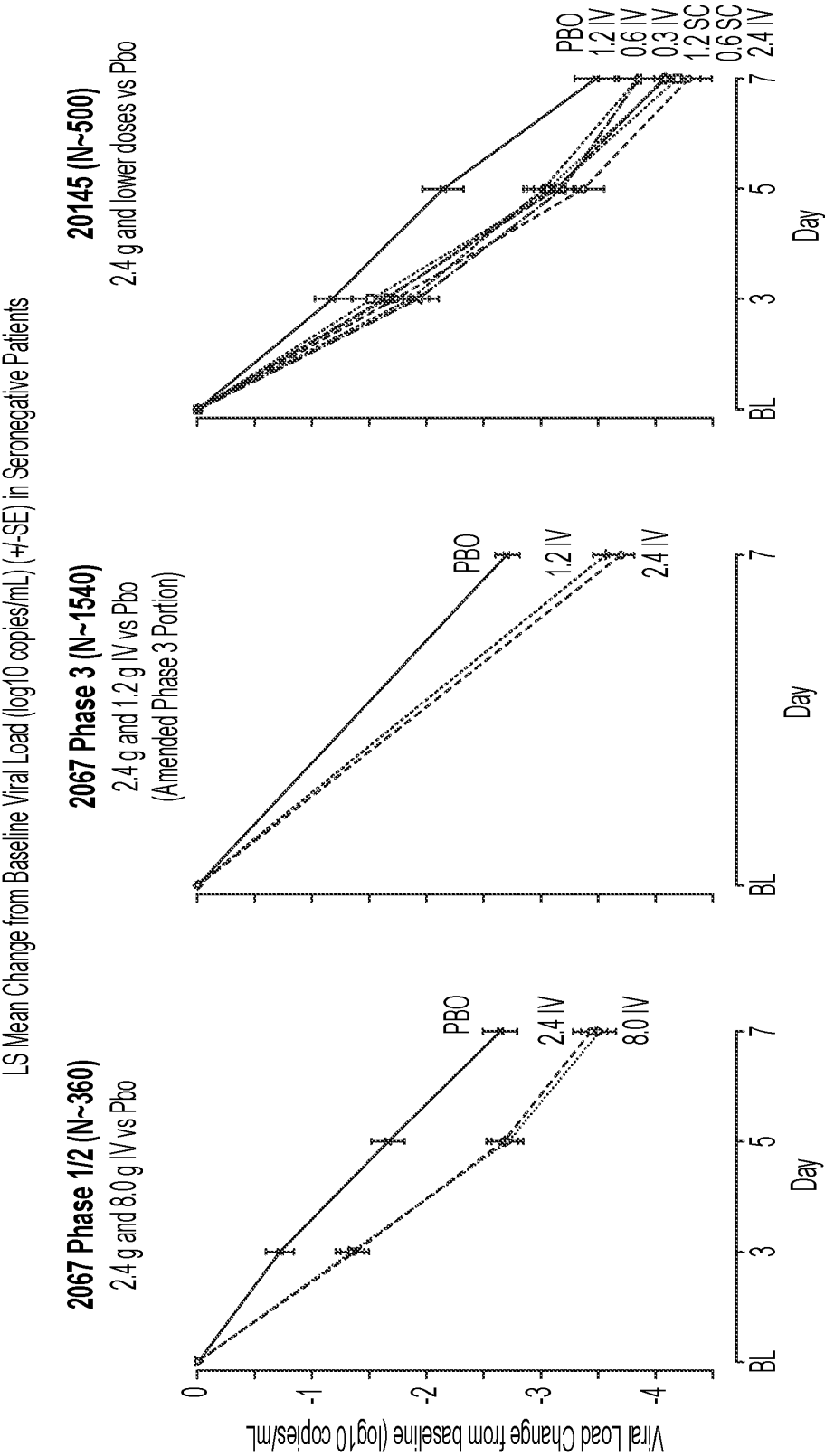


FIG. 48

	Placebo IV (N=57)	REGEN-COV 300 mg IV (N=115)	REGEN-COV 600 mg IV (N=114)	REGEN-COV 1200 mg IV (N=116)	REGEN-COV 2400 mg IV (N=115)
Total number of TEAE	11	13	17	25	9
Total number of grade 3 or 4 TEAE	1	0	1	1	0
Total number of SAE	0	0	0	1	1
Total number of AESI	2	0	1	2	0
Patients with any TEAE	10 (17.5%)	10 (8.7%)	16 (14.0%)	22 (19.0%)	9 (7.8%)
Patients with any grade 3 or 4 TEAE	1 (1.8%)	0	1 (0.9%)	1 (0.9%)	0
Patients with any SAE	0	0	0	1 (0.9%)	1 (0.9%)
Patients with any AESI	1 (1.8%)	0	1 (0.9%)	2 (1.7%)	0
Patients with infusion-related reaction (grade ≥ 2) through day 4	0	0	0	0	0
Patients with injection-site reactions (grade ≥ 3) through day 4	0	0	0	0	0
Patients with hypersensitivity reactions (grade ≥ 2) through day 4	0	0	0	0	0
Patients with any TEAE leading to death	0	0	0	0	0
Patients with any TEAE leading to withdrawal from the study medication	0	0	0	0	1 (0.9%)
Patients with any TEAE leading to study infusion interruption	0	0	0	0	0

FIG. 49

AESI include all grade ≥ 2 IRR, grade ≥ 3 ISR, grade ≥ 2 hypersensitivity reactions, and any TEAE that led to hospitalization of ER visit regardless of relation to COVID-19

	Placebo SC (N=58)	REGEN-COV 600 mg SC (N=114)	REGEN-COV 1200 mg SC (N=114)
Total number of TEAE	11	5	14
Total number of grade 3 or 4 TEAE	0	0	0
Total number of SAE	0	0	0
Total number of AESI	0	0	1
Patients with any TEAE	6 (10.3%)	5 (4.4%)	12 (10.5%)
Patients with any grade 3 or 4 TEAE	0	0	0
Patients with any SAE	0	0	0
Patients with any AESI	0	0	1 (0.9%)
Patients with infusion-related reaction (grade ≥ 2) through day 4	0	0	0
Patients with injection-site reactions (grade ≥ 3) through day 4	0	0	0
Patients with hypersensitivity reactions (grade ≥ 2) through day 4	0	0	0
Patients with any TEAE leading to death	0	0	0
Patients with any TEAE leading to withdrawal from the study medication	0	0	0
Patients with any TEAE leading to study infusion interruption	0	0	0

FIG. 50

2067 Analysis Set (symptomatic, ≥1 risk factor)		Original Ph3 Placebo	Original Ph3 2400 mg	Original Ph3 8000 mg	Amended Ph3 Placebo	Amended Ph3 1200 mg	Amended Ph3 2400 mg
mFAS	Baseline, mean (SD)	6.70 (1.664)	6.62 (1.630)	6.64 (1.671)	6.63 (1.823)	6.73 (1.863)	6.80 (1.765)
	LSMEAN Change (SE)	-2.63 (0.09)	-3.49 (0.09)	-3.49 (0.09)	-2.64 (0.09)	-3.35 (0.09)	-3.51 (0.09)
	Difference from Placebo		-0.87 (0.10)	-0.87 (0.10)		-0.71 (0.09)	-0.87 (0.09)
	p-value		<0.0001	<0.0001		<0.0001	<0.0001
Seronegative	Baseline, mean (SD)	7.19 (1.370)	7.10 (1.346)	7.20 (1.337)	7.18 (1.550)	7.27 (1.611)	7.23 (1.560)
	LSMEAN Change (SE)	-2.69 (0.11)	-3.79 (0.10)	-3.84 (0.11)	-2.70 (0.11)	-3.56 (0.11)	-3.70 (0.11)
	Difference from Placebo		-1.10 (0.12)	-1.15 (0.12)		-0.86 (0.11)	-1.00 (0.11)
	p-value		<0.0001	<0.0001		<0.0001	<0.0001
Seropositive	Baseline, mean (SD)	5.18 (1.634)	5.35 (1.661)	5.30 (1.696)	5.07 (1.671)	5.27 (1.728)	5.32 (1.695)
	LSMEAN Change (SE)	-2.08 (0.19)	-2.49 (0.18)	-2.36 (0.18)	-2.36 (0.16)	-2.53 (0.15)	-2.85 (0.15)
	Difference from Placebo		-0.41 (0.21)	-0.28 (0.21)		-0.16 (0.19)	-0.49 (0.19)
	p-value		0.0527	0.1802		0.3799	0.0094

FIG. 51

20145 Analysis Set (symptomatic, no risk factor or asymptomatic)		20145 Placebo (IV/SC)	20145 2400 mg IV	20145 1200 mg IV	20145 600 mg IV	20145 300 mg IV	20145 1200 mg SC	20145 600 mg SC
mFAS	Baseline, mean (SD)	6.81 (1.509)	6.43 (1.948)	6.56 (1.745)	6.94 (1.847)	6.88 (1.784)	6.73 (1.790)	6.86 (1.822)
	LSMEAN Change (SE)	-3.39 (0.18)	-4.08 (0.17)	-3.83 (0.17)	-3.62 (0.18)	-3.87 (0.17)	-3.94 (0.17)	-3.86 (0.17)
	Difference from Placebo		-0.69 (0.24)	-0.44 (0.24)	-0.22 (0.25)	-0.48 (0.24)	-0.54 (0.25)	-0.47 (0.24)
	p-value		0.0050	0.0714	0.3735	0.0505	0.0281	0.0547
Seronegative	Baseline, mean (SD)	7.02 (1.389)	7.25 (1.602)	7.15 (1.518)	7.43 (1.451)	7.22 (1.578)	7.18 (1.564)	7.40 (1.540)
	LSMEAN Change (SE)	-3.48 (0.19)	-4.28 (0.21)	-3.84 (0.20)	-3.85 (0.21)	-4.08 (0.19)	-4.09 (0.20)	-4.19 (0.20)
	Difference from Placebo		-1.81 (0.29)	-0.36 (0.28)	-0.37 (0.28)	-0.60 (0.27)	-0.62 (0.28)	-0.71 (0.28)
	p-value		0.0052	0.1975	0.1901	0.0270	0.0261	0.0101
Seropositive	Baseline, mean (SD)	5.75 (1.758)	4.88 (1.525)	5.18 (1.650)	4.83 (1.865)	5.71 (2.137)	4.95 (1.795)	4.90 (1.519)
	LSMEAN Change (SE)	-3.46 (0.49)	-3.54 (0.31)	-3.23 (0.34)	-2.63 (0.41)	-3.00 (0.41)	-3.70 (0.42)	-3.03 (0.45)
	Difference from Placebo		-0.08 (0.56)	0.24 (0.60)	0.83 (0.64)	0.46 (0.64)	-0.24 (0.65)	0.43 (0.67)
	p-value		0.8939	0.6921	0.1971	0.4714	0.7167	0.5157

FIG. 51 (Cont.)

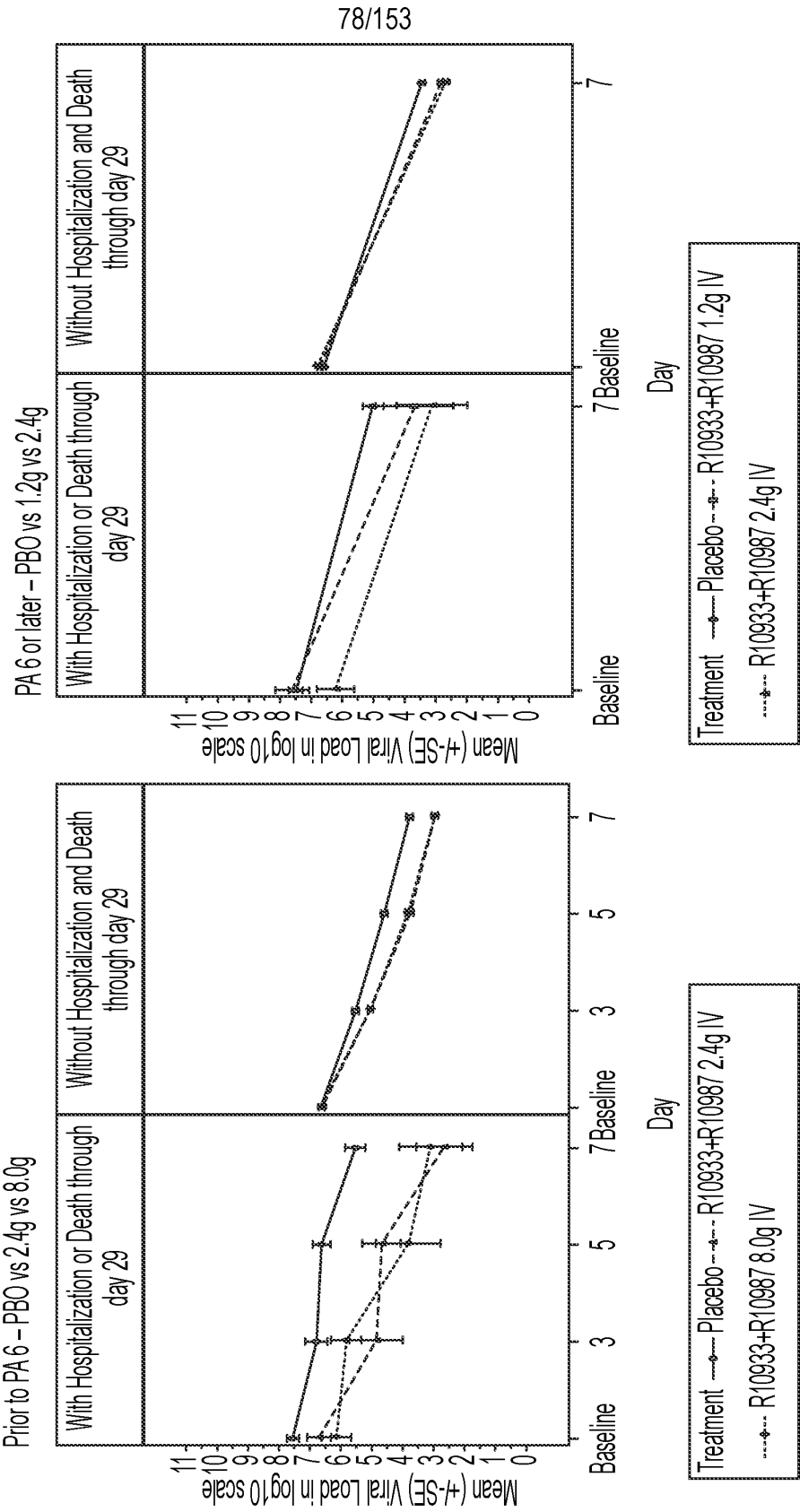


FIG. 52

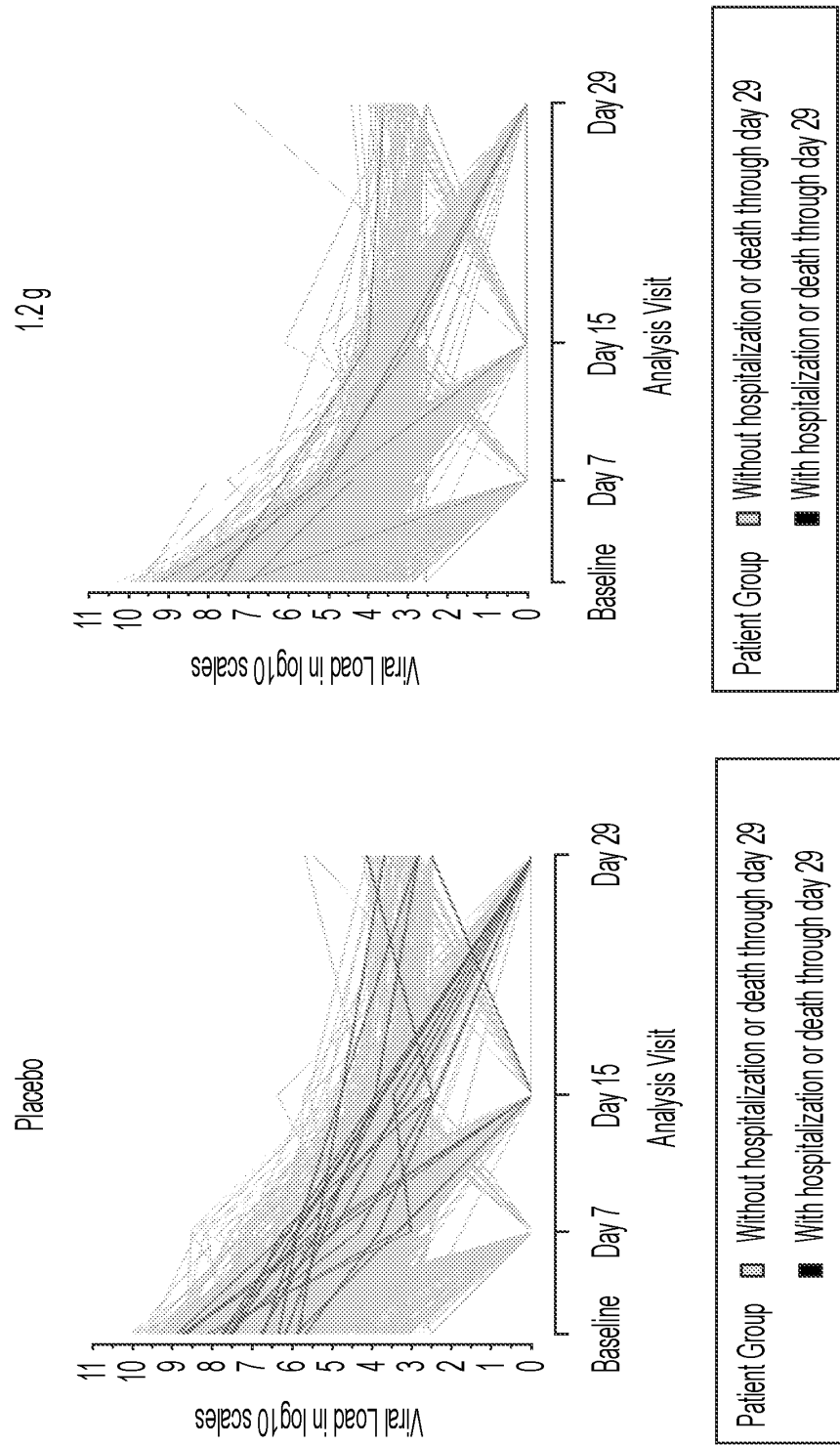


FIG. 53

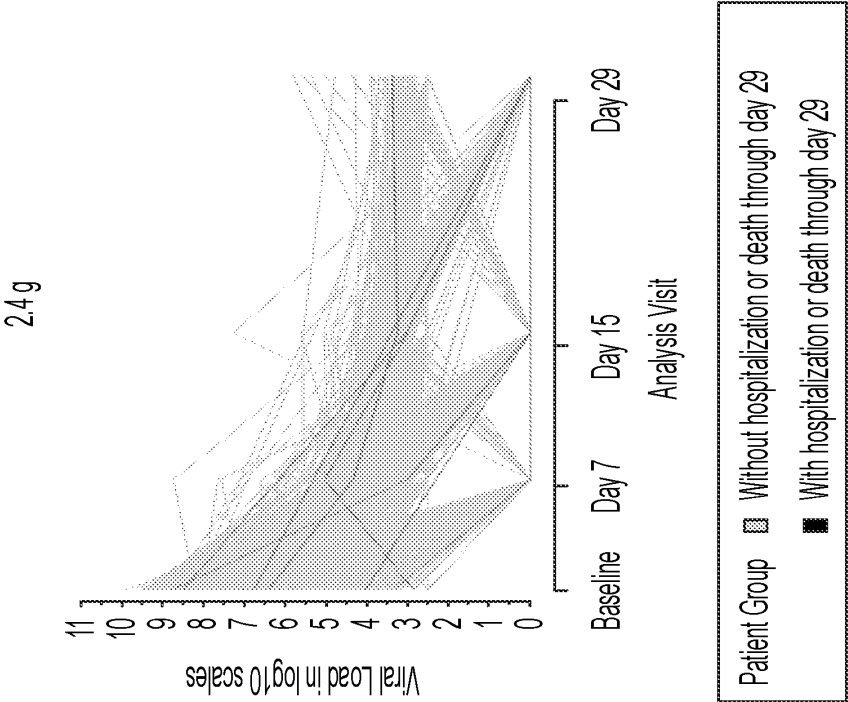


FIG. 53 (Cont.)

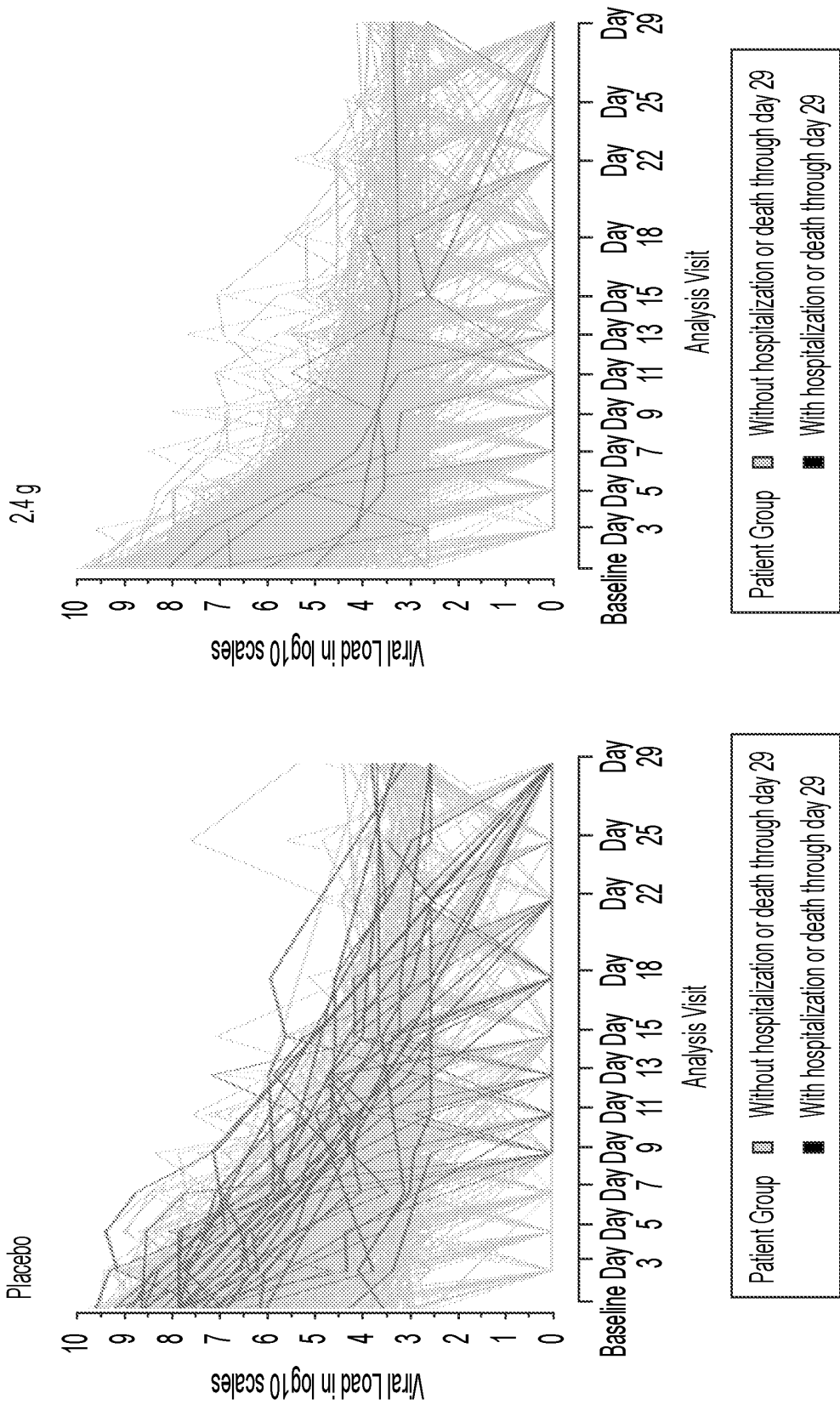


FIG. 54

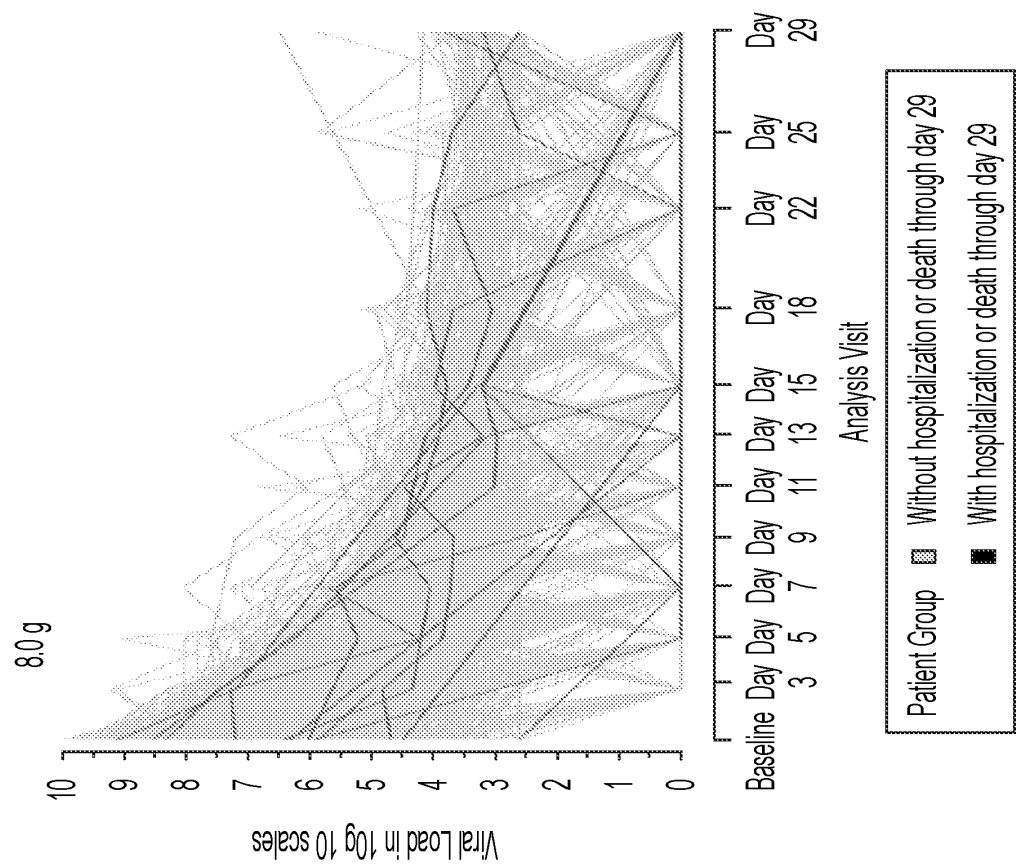


FIG. 54 (Cont.)

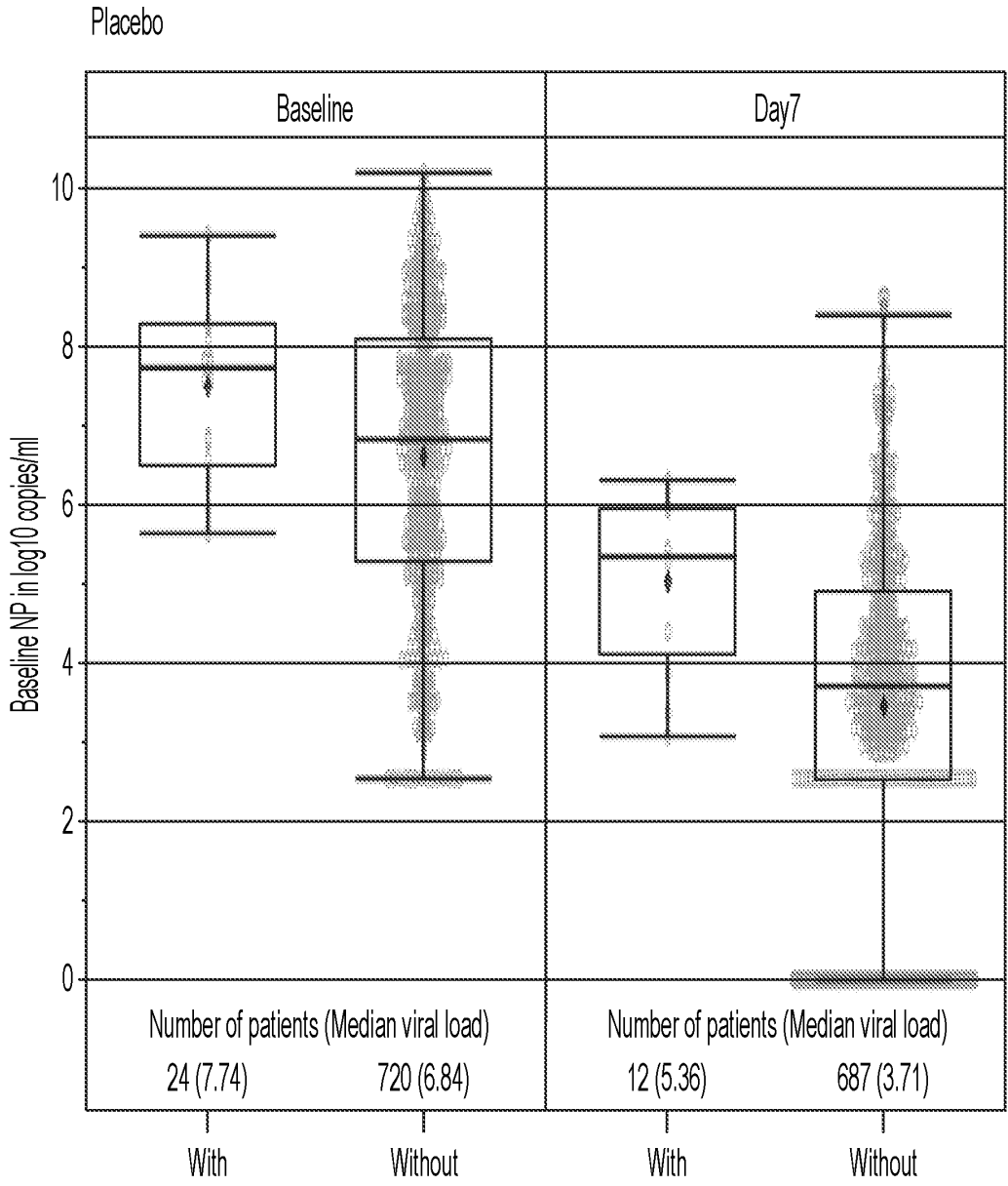


FIG. 55

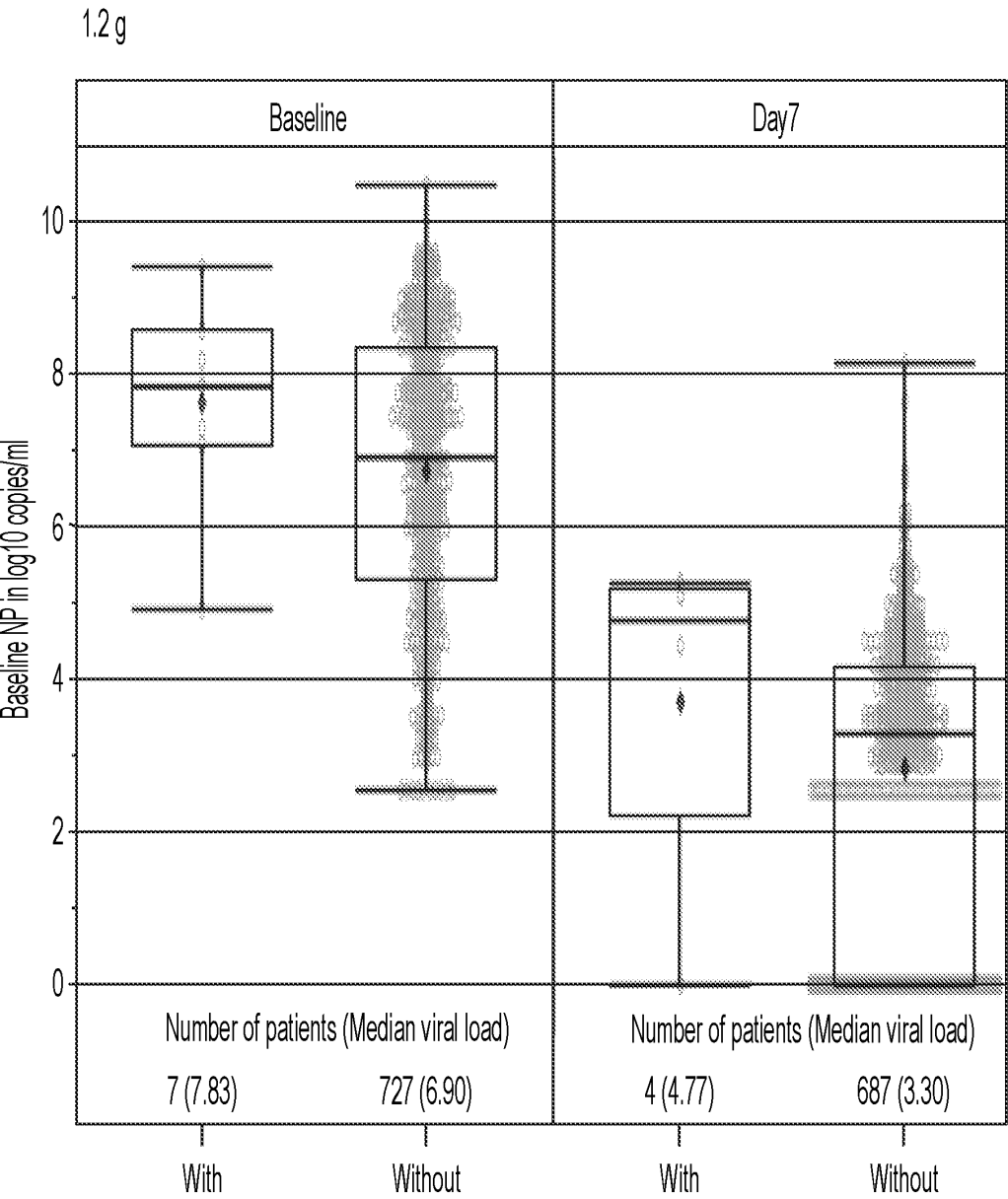


FIG. 55 (Cont.)

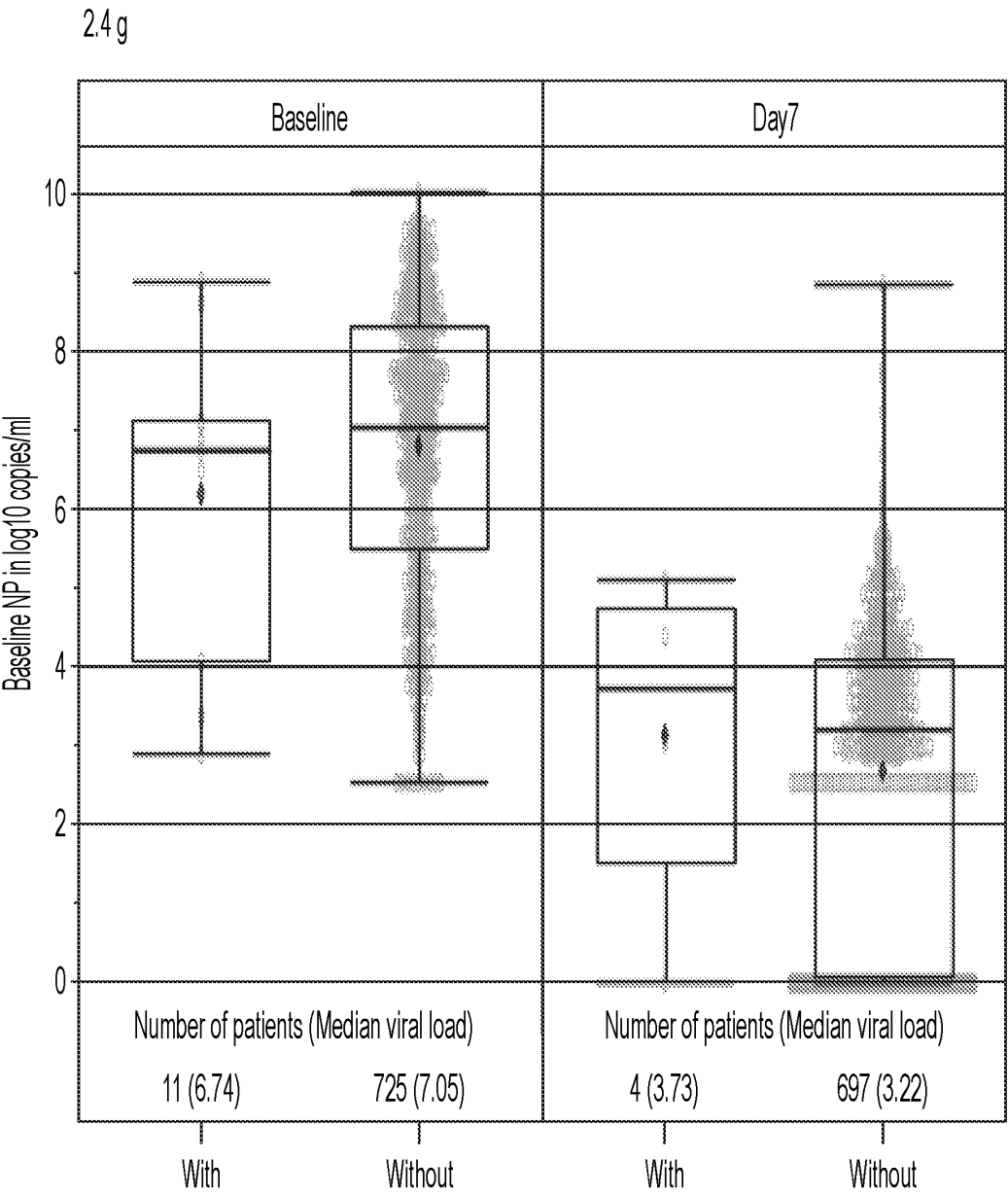


FIG. 55 (Cont.)

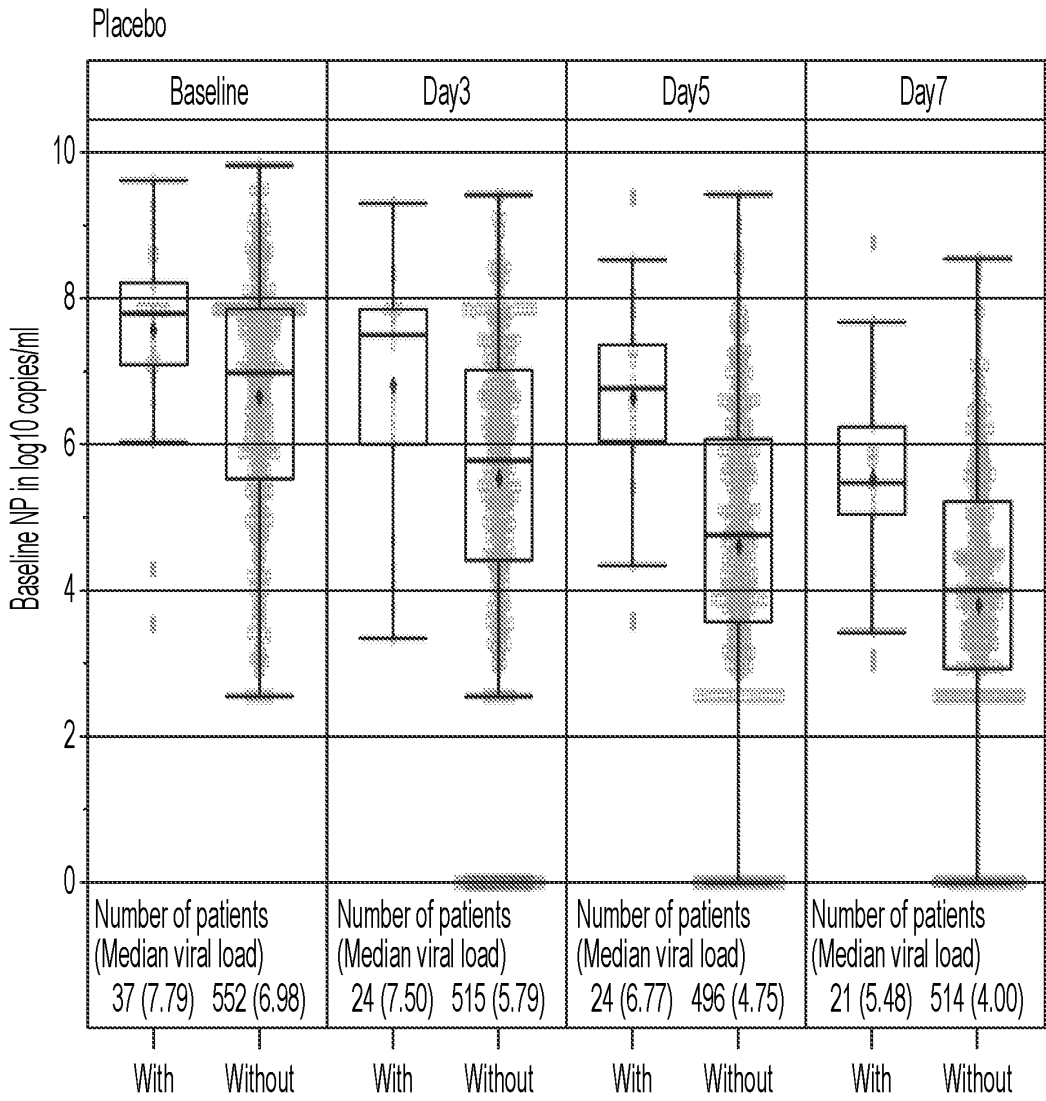


FIG. 56

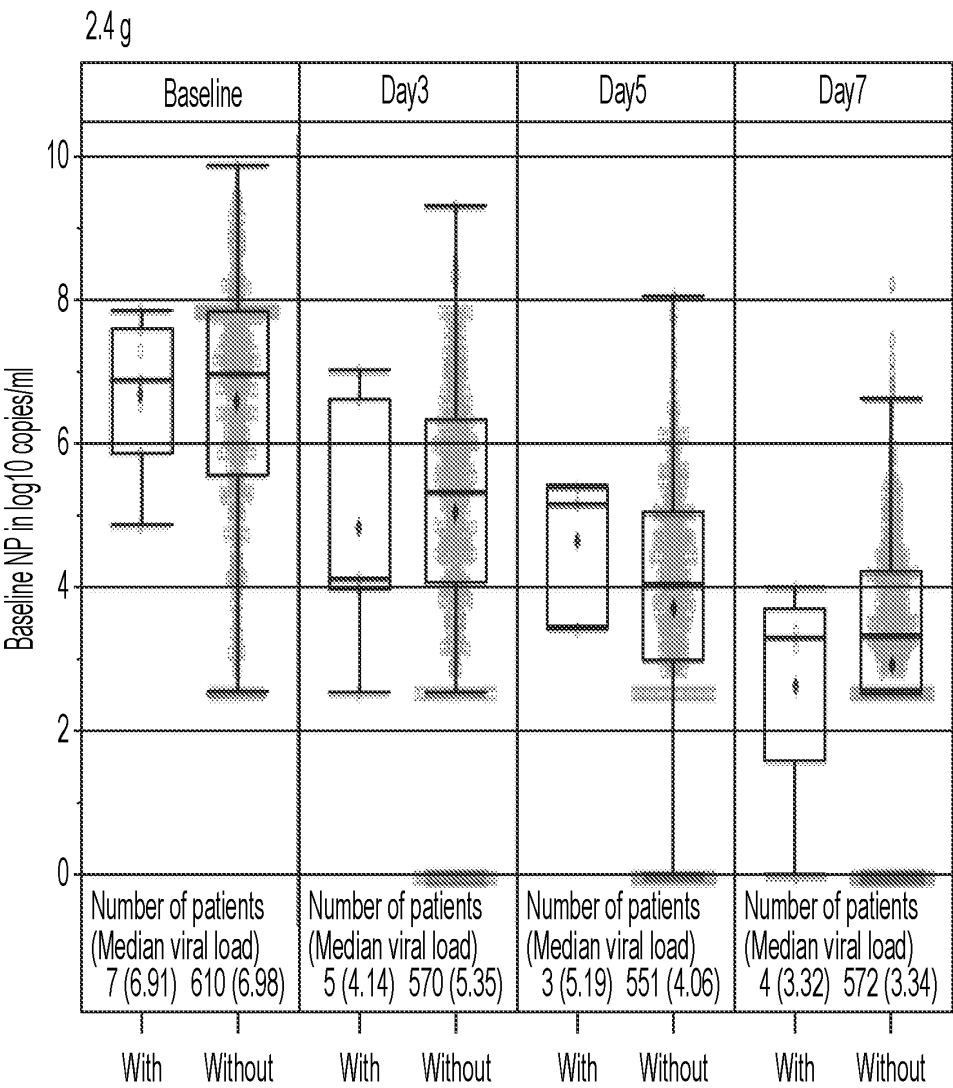


FIG. 56 (Cont.)

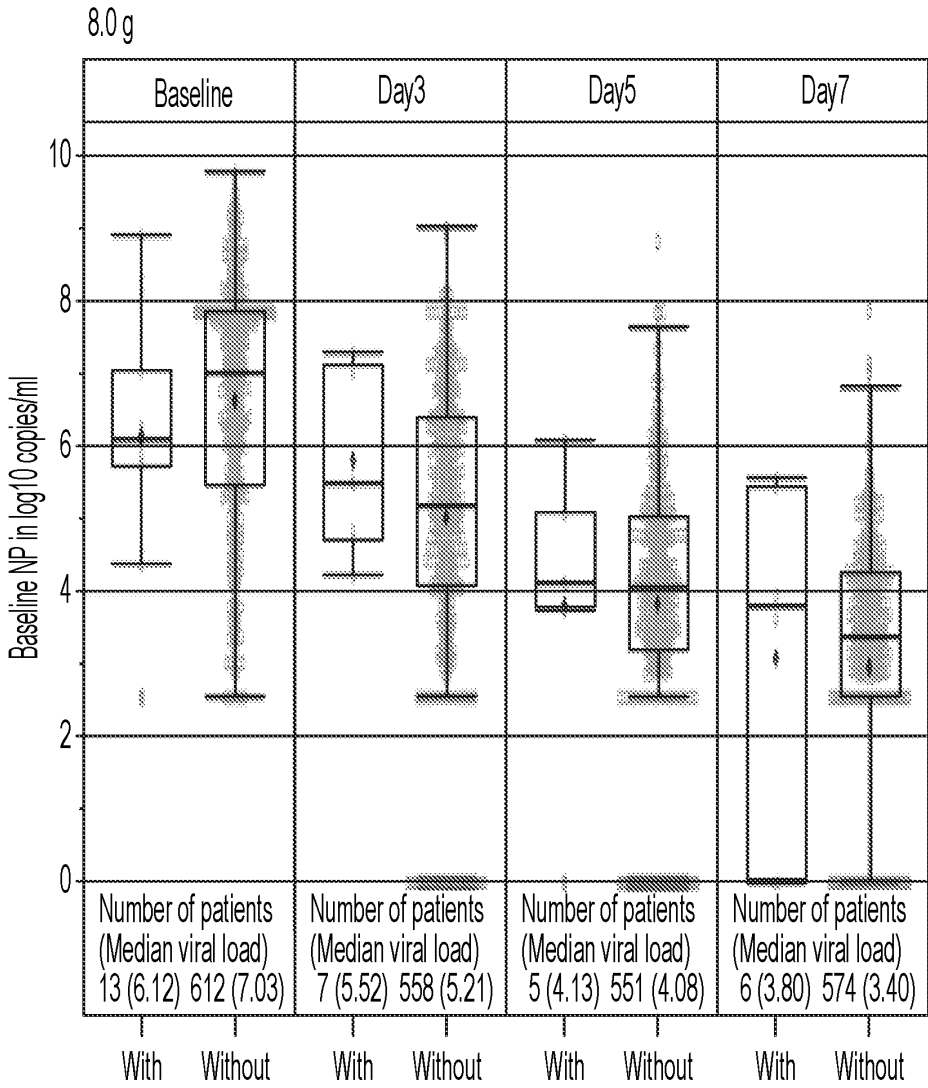


FIG. 56 (Cont.)

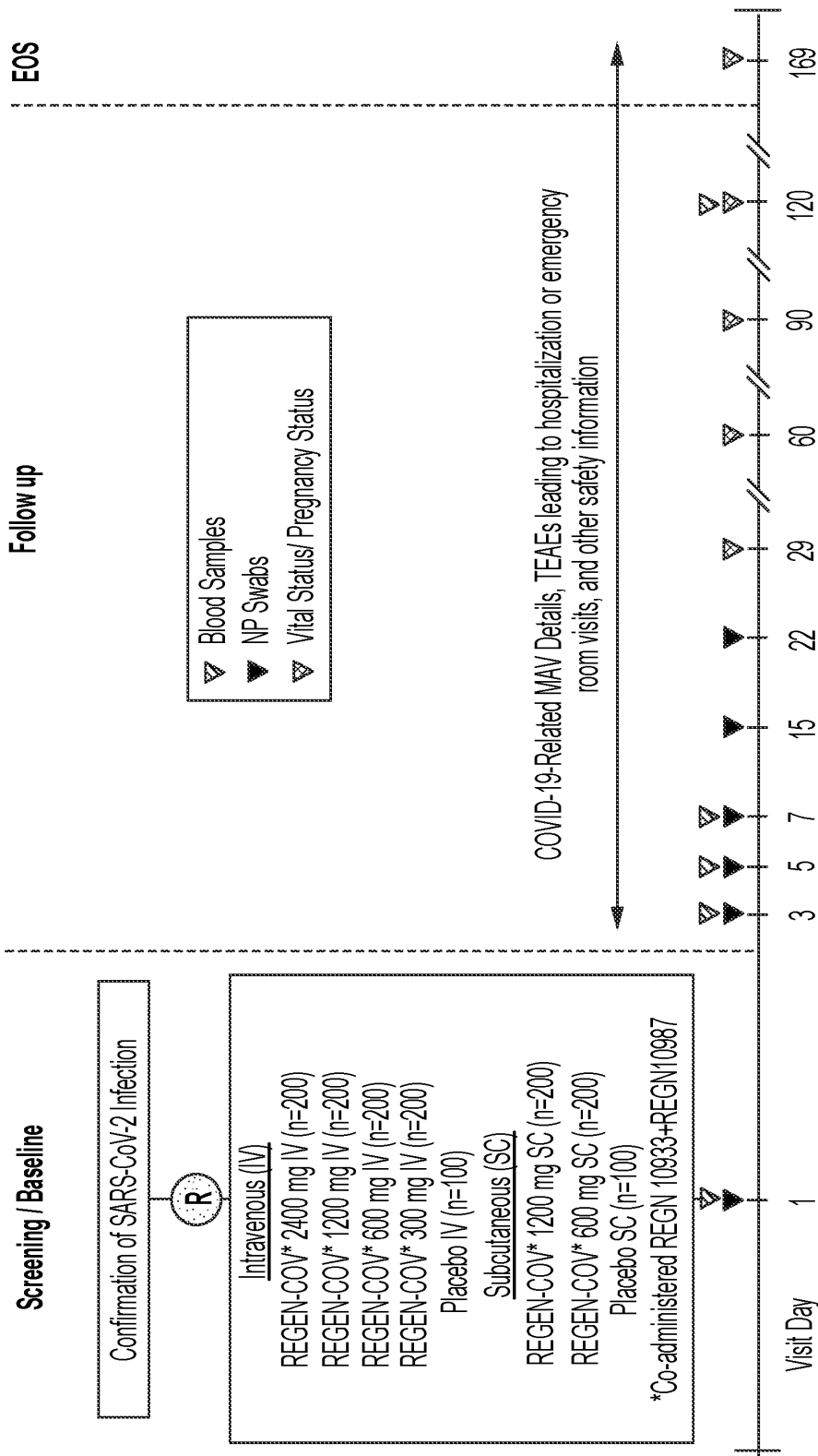


FIG. 57

Baseline Serology	EVENT	Baseline Viral Load (Log10 Copies/mL)	Day 7 Viral Load (Log10 Copies/mL)	Change to Day 7 in Viral Load (Log10 Copies/mL)
All	No	6.60	3.45	-3.14
All	Yes	7.50 (n=62)	5.03 (n=43)	-2.69
SeroNeg	No	7.14 (n=905)	4.04 (n=861)	-3.02
SeroNeg	Yes	7.61 (n=50)	5.40 (n=35)	-1.83
SeroPos	No	5.06 (n=289)	2.47 (n=282)	-2.52
SeroPos	Yes	7.06 (n=12)	5.08 (n=8)	-1.56

Results not QC'd

FIG. 58

Hypothesis Testing Hierarchy	Comparison	Treatment Effect
1. Incidence of Symptomatic Infection [broad term (%)]	REGEN-COV vs PBO	81% rel. risk reduction ; 11/753 (1.5%) vs 59/752 (7.8%) Odds ratio (95% CI)*: 0.17 (0.09, 0.33); p<0.0001
2. Incidence of Viral Load >10 ⁴ (copies/mL) (%)	REGEN-COV vs PBO	86% rel. risk reduction ; 12/745 (1.6%) vs 85/749 (11.3%) Odds ratio (95% CI)*: 0.13 (0.07, 0.24); p<0.0001
3. Number of weeks of symptomatic infection	REGEN-COV vs PBO	93% reduction ; 12.9 vs 187.7 (weeks); Per 1000 subjects: 17 vs 249.6 (weeks), p<0.0001
4. Number of weeks of Viral Load >10 ⁴ (copies/mL)	REGEN-COV vs PBO	90% reduction ; 14 vs 136 (weeks); Per 1000 subjects: 18.8 vs 181.6 (weeks), p<0.0001
5. Number of weeks of infection regardless of symptoms	REGEN-COV vs PBO	82% reduction ; 41 vs 231 (weeks) Per 1000 subjects: 54.4 vs 307.2 (weeks), p<0.0001
6. Incidence of any RT-qPCR positive Infection (%)	REGEN-COV vs PBO	66% reduction ; 36/753 (4.8%) vs 107/752 (14.2%) Odds ratio (95% CI)*: 0.31 (0.21, 0.46), p<0.0001
7. Index linkage to 2067 for incidence of qPCR positive infection (%) (index case placebo vs index case REGEN-COV)	Index Case (2067): REGEN -COV VS PBO	No reduction ; 23/116 (19.8%) vs 10/51 (19.6%) Not significant

*Based on the logistic regression model adjusted by region (US vs ex-US) and age group (12 to <50 vs >=50 years)

Note: Duration of disease burden endpoints are based on stratified Wilcoxon rank sum test (Van Elteren test) with region (US vs ex-US) and age group (12 to <50 vs >=50 years) as strata.

FIG. 59

Symptomatic Infection Endpoints	Placebo N=752	REGEN-COV N=753	Observed Risk Reduction (%)	Odds Ratio (95% CI)*	p-Value
Broad term Symptomatic infection rate (%) (primary)	59 (7.8%)	11 (1.5%)	80.8%	0.17 (0.09, 0.33)	<0.0001
CDC Definition Symptomatic infection rate (%)	46 (6.1%)	6 (0.8%)	86.9%	0.12 (0.05, 0.29)	<0.0001**
Strict term Symptomatic infection rate (%)	22 (2.9%)	2 (0.3%)	89.7%	0.09 (0.02, 0.37)	0.0010**

Prevention Cohort (Cohort A): asymptomatic, RT-PCR negative, seronegative at baseline
*Based on the logistic regression model adjusted by region (US vs ex-US) and age group (12 to <50 vs >=50 years)
** Nominal p-Value

FIG. 60

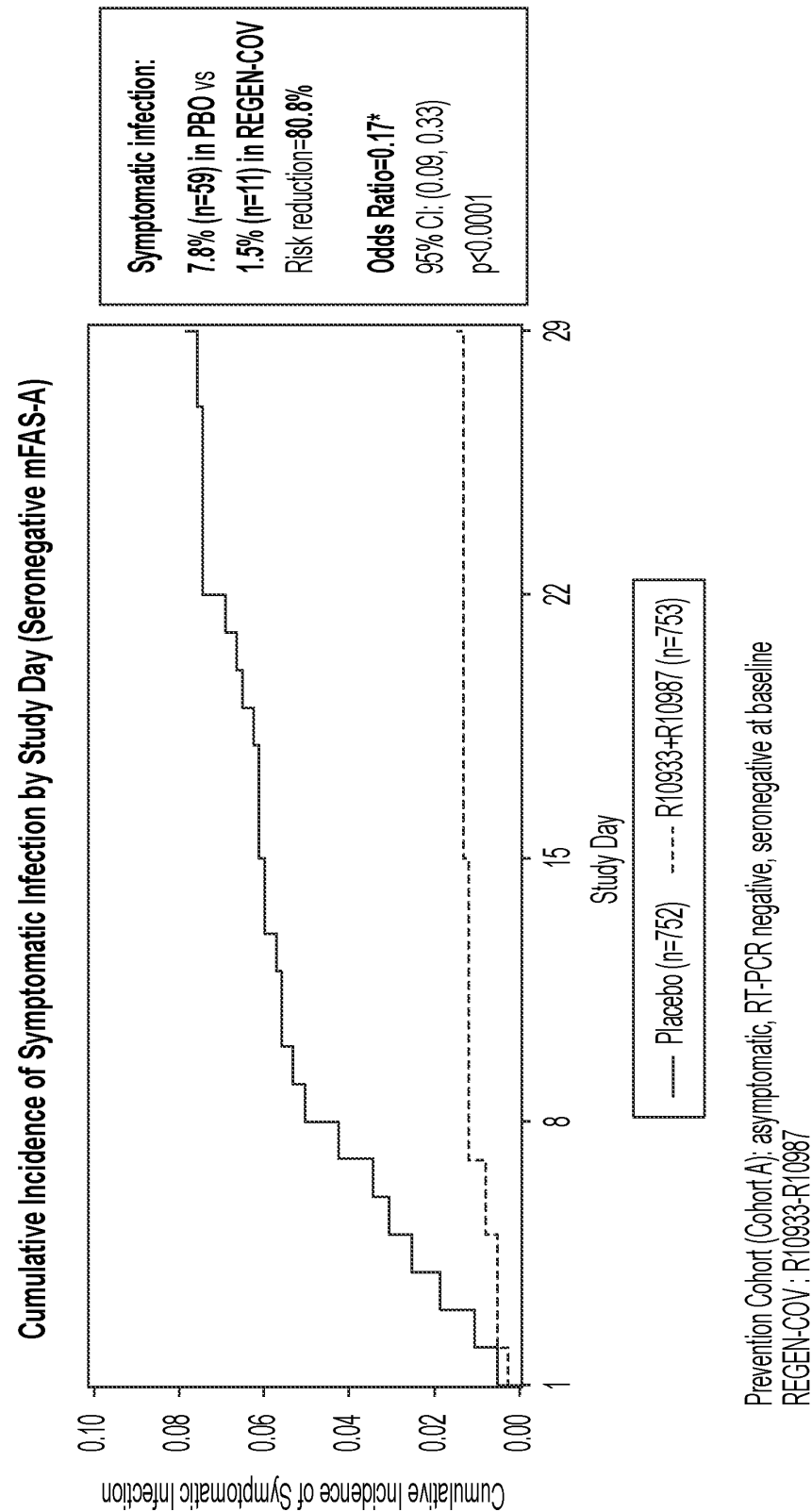


FIG. 61

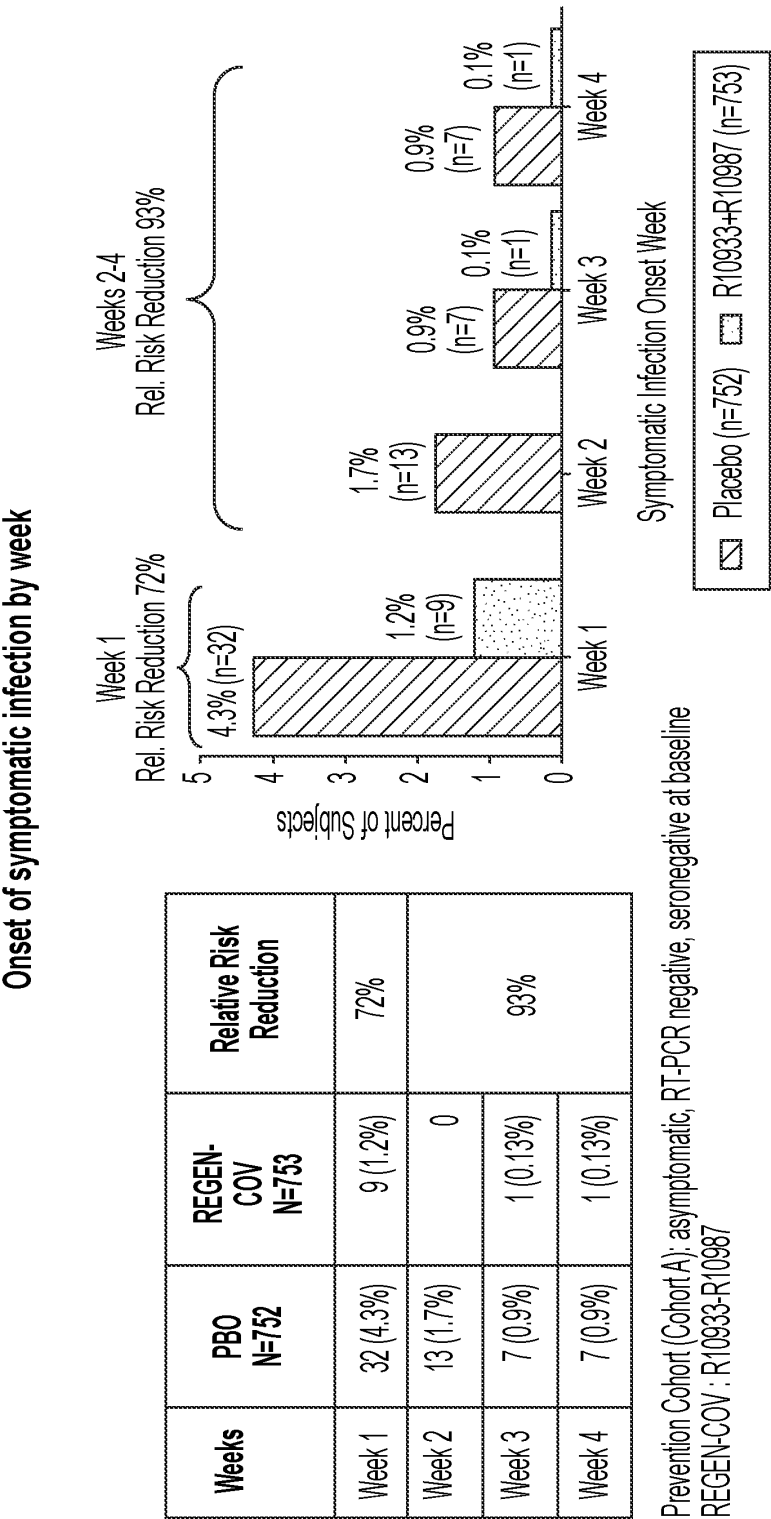


FIG. 62

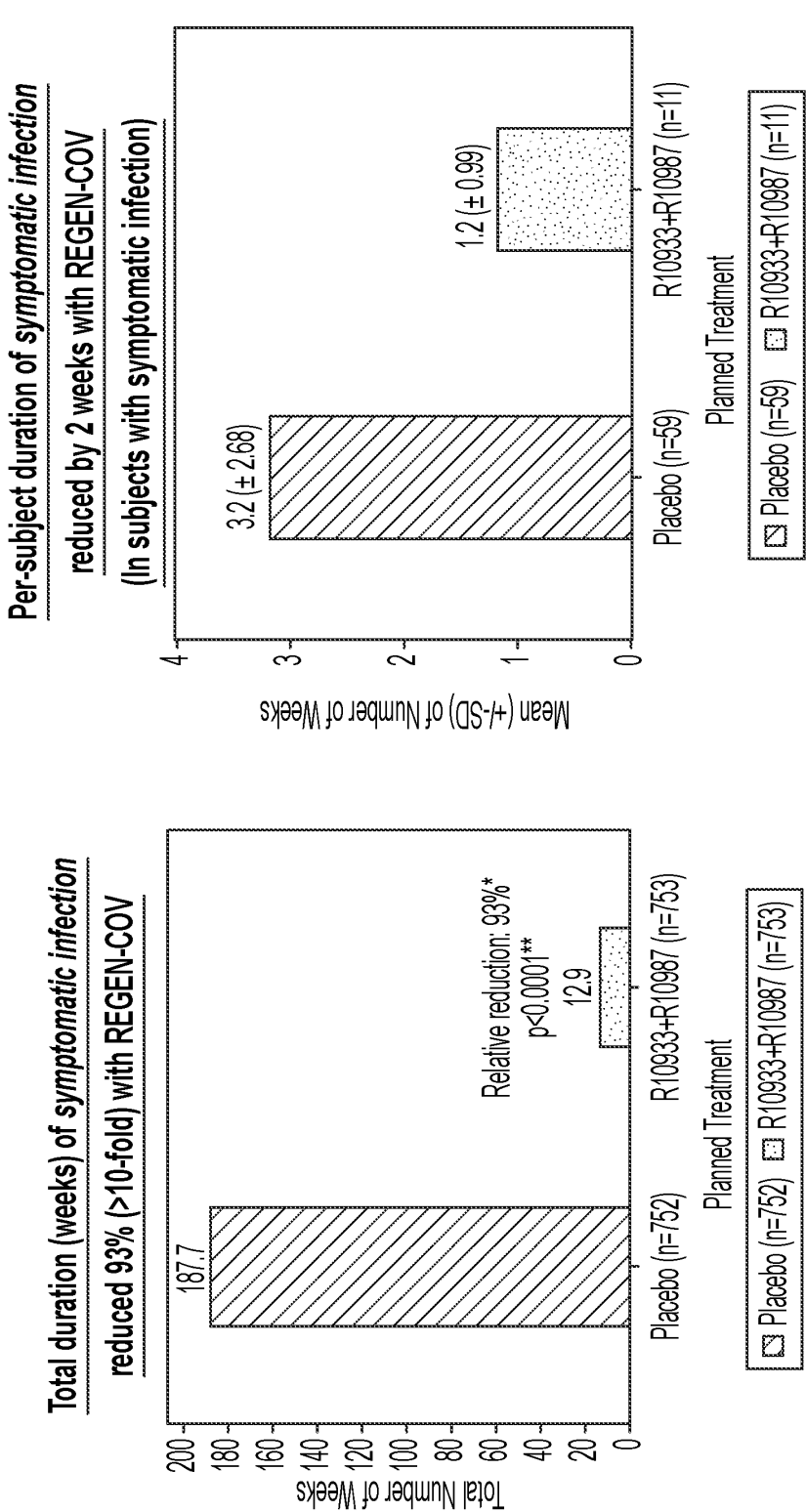
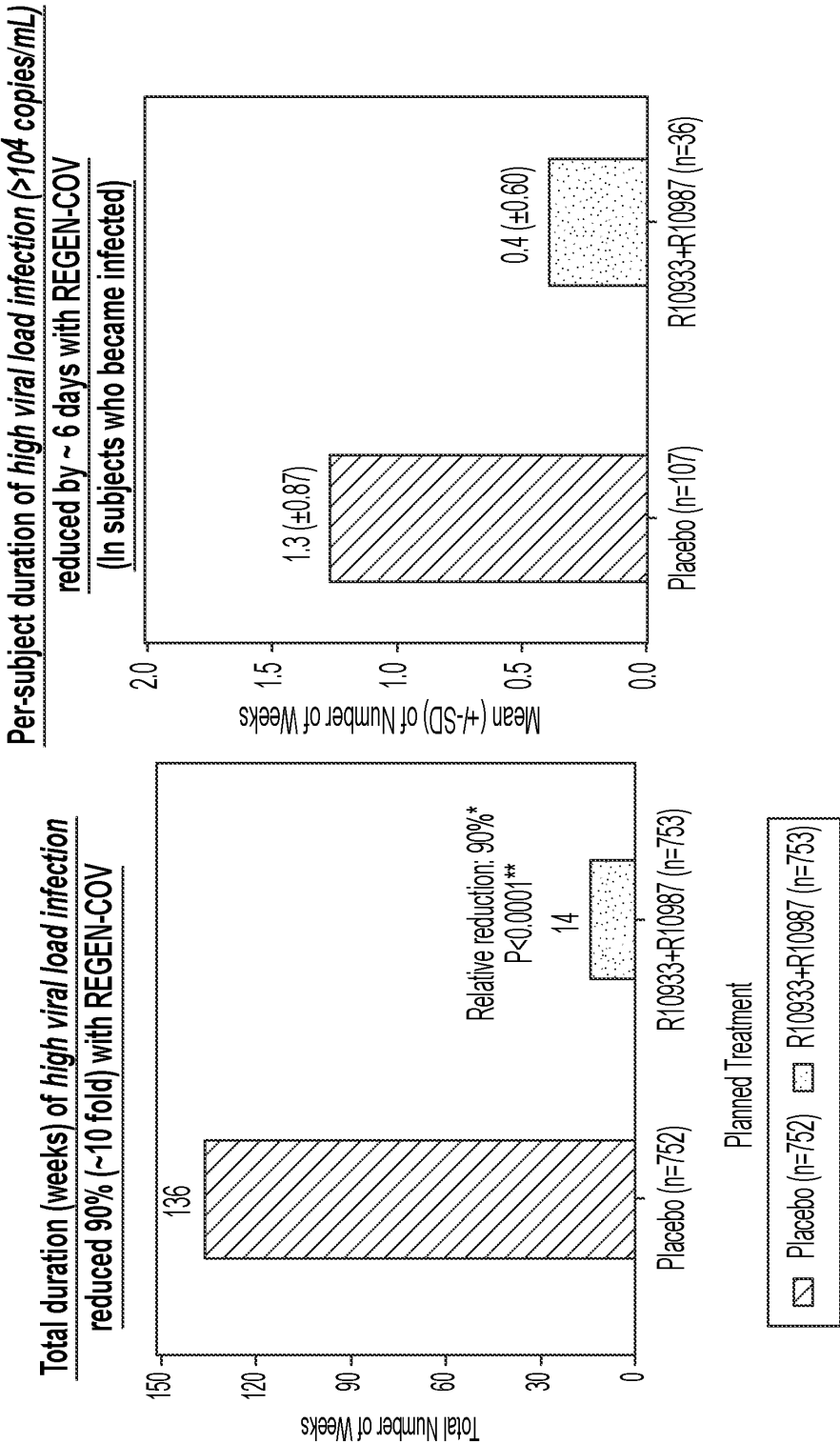


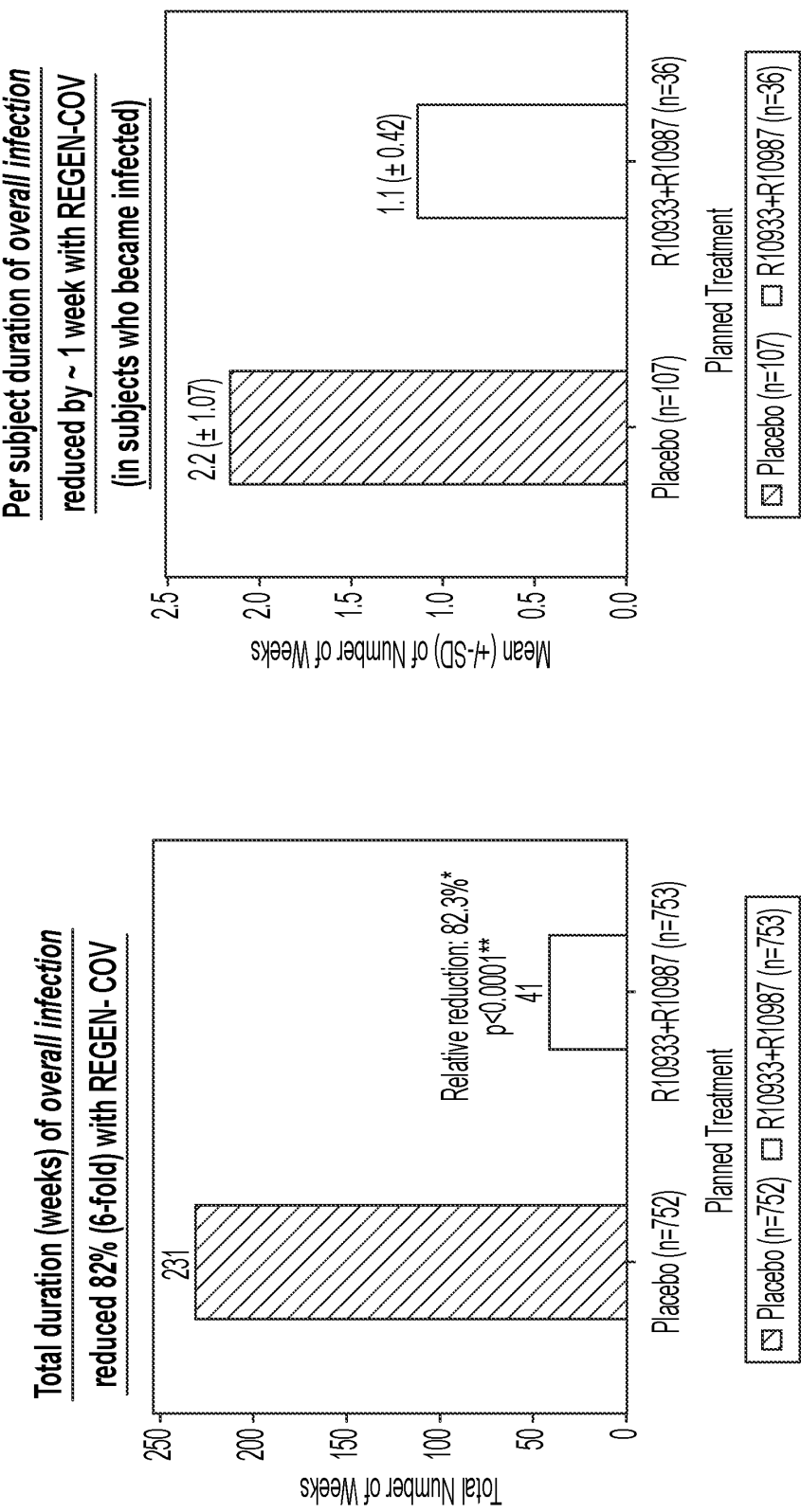
FIG. 63



*Based on the normalized weeks per 1000 subjects;
**Based on the stratified Wilcoxon rank sum test (Van Elteren test) with region (US vs ex-US) and age group (12 to <50 vs >=50 years) as strata.
REGEN-COV : R10933-R10987

FIG. 64

97/153



* Based on the normalized weeks per 1000 subjects;
** Based on the stratified Wilcoxon rank sum test (Van Elteren test) with region (US vs ex-US) and age group (12 to <50 vs >=50 years) as strata.
REGEN-COV : R10933-R10987

FIG. 65

Hypothesis Testing Hierarchy	Comparison	Treatment Effect
1. Symptomatic infection rate (%)	REGEN-COV vs PBO	31.4% relative risk reduction; 29/100 (29.0%) vs 44/104 (42.3%) Odds ratio (95% CI)*: 0.54 (0.30, 0.97); p=0.0380
2. Weeks of symptomatic infection	REGEN-COV vs PBO	45.3% relative risk reduction; 89.6 vs 170.3 (weeks) Per 1000 subjects: 895.7 vs 1637.4 (weeks), p=0.0273
3. Weeks of Viral Load >10 ⁴ (copies/mL)	REGEN-COV vs PBO	39.7% relative risk reduction; 48 vs 82 (weeks) Per 1000 subjects: 489.8 vs 811.9 (weeks), p=0.0010

Seronegative Pre-emptive therapy Cohort	Placebo	REGEN-COV	Risk Reduction	p-Value
All subjects	44/104 (42.3%)	29/100 (29.0%)	31.4%	0.0380
Day 2 and beyond	37/97 (38.1%)	19/90 (21.1%)	44.6%	0.0094
Day 3 and beyond	22/82 (26.8%)	8/79 (10.1%)	62.3%	0.0075
Day 4 and beyond	22/82 (26.8%)	5/76 (6.6%)	75.4%	0.0014

*Based on the logistic regression model adjusted by region (US vs ex-US) and age group (12 to <50 vs ≥50 years)

Note: Duration of disease burden endpoints are based on stratified Wilcoxon rank sum test (Van Elteren test) with region (US vs ex-US) and age group (12 to <50 vs ≥50 years) as strata.

FIG. 66

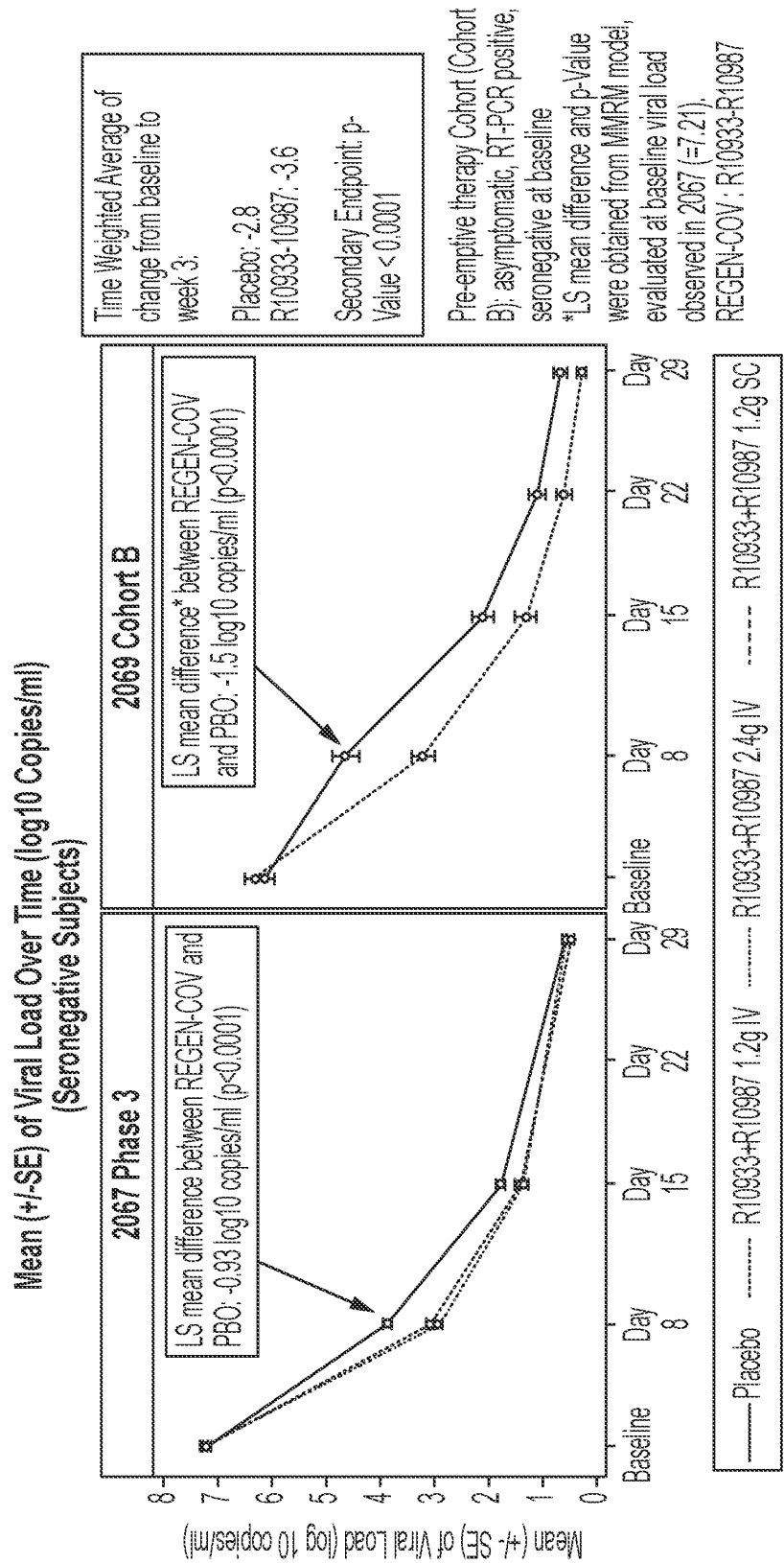


FIG. 67

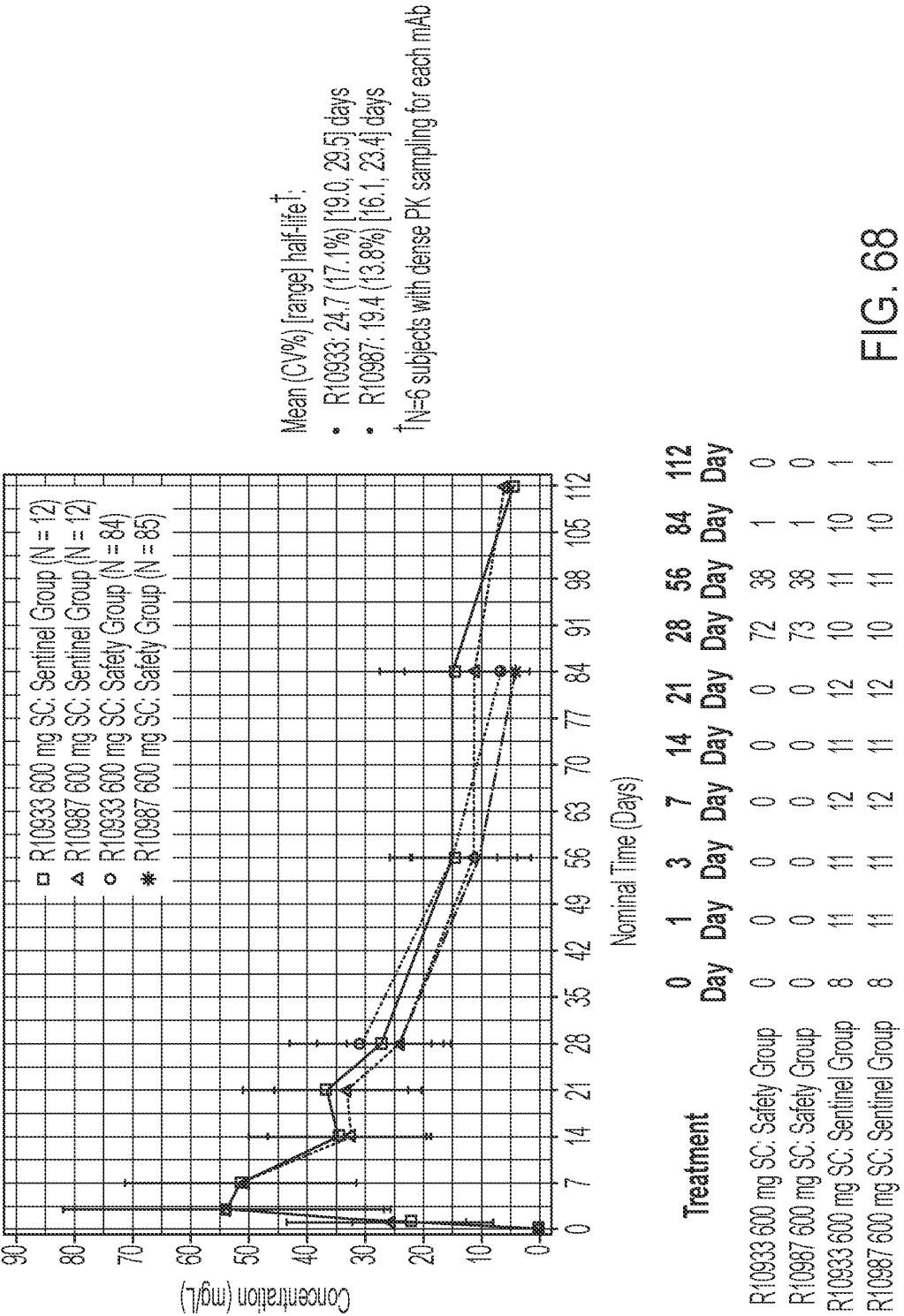


FIG. 68

Overall study period, including seronegative and seropositive subjects	Prevention Cohort (Cohort A)		Pre-emptive therapy Cohort (Cohort B)	
	Placebo N=1306	REGEN-COV N=1311	Placebo N=156	REGEN-COV N=155
Subjects with any TEAEs	379 (29.0%)	265 (20.2%)	75 (48.1%)	52 (33.5%)
Subjects with any AESI (grade 3 or greater injection site reaction or hypersensitivity reaction)	0	0	0	0
Subjects with any serious TEAE	15 (1.1%)	10 (0.8%)	4 (2.6%)	0
Deaths	2 (0.2%)	2 (0.2%)	0	0
Injection site reaction	19 (1.5%)	55 (4.2%)	1 (0.6%)	6 (3.9%)
Subjects with treatment/study withdrawn due to TEAEs	0	0	0	0

Comparatively more subjects experienced TEAEs in placebo groups in both Cohort A and B in comparison with study treatment. Injection site reactions reported with REGEN-COV were mild to moderate in severity.

FIG. 69

Overall study period, including seronegative and seropositive subjects	Prevention Cohort (Cohort A)		Pre-emptive therapy Cohort (Cohort B)	
	Placebo N=1306	REGEN-COV N=1311	Placebo N=156	REGEN-COV N=155
COVID-19	112 (8.6%)	15 (1.1%)	49 (31.4%)	34 (21.9%)
Asymptomatic COVID-19	108 (8.3%)	54 (4.1%)	12 (7.7%)	7 (4.5%)
Headache	46 (3.5%)	24 (1.8%)	1 (0.6%)	0
Injection site reaction	19 (1.5%)	55 (4.2%)	1 (0.6%)	6 (3.9%)

- * Most frequent TEAEs were COVID-19 related
- * TEAEs occurred more frequently in the placebo group, consistent with the benefit of REGEN-COV

FIG. 70

Overall study period, including seronegative and seropositive subjects	Prevention Cohort (Cohort A) Subjects with at least 1 SAE		Pre-emptive therapy Cohort (Cohort B) Subjects with at least 1 SAE	
	Placebo N=1306	REGEN-COV N=1311	Placebo N=156	REGEN-COV N=155
Patients with any SAE by SOC/PT	15 (1.1%) * Sepsis * Pneumonia (not related to COVID-19) * Appendicitis * Scrotal abscess + UTI * Cardiac arrest * Abdominal pain * Gun shot wound * Breast cancer * Mania + Suicidal ideation * Essential hypertension * COVID-19 x 4 * COVID-19 pneumonia x 2	10 (0.8%) * Gastroenteritis * Pneumonia (not related to COVID-19) * Sepsis * Soft tissue infection * Appendicitis * Cardiac failure congestive + Acute myocardial infarction + Cholecystitis acute * Abdominal pain upper * Sudden death * Ankle+ Tibia+ Foot fracture * Cervix carcinoma recurrent	4 (2.6%) * Acute pancreatitis * COVID-19 x 2 * COVID-19 pneumonia	0
Deaths by SOC/PT	2 (0.2%) * Cardiac arrest (not related to COVID-19) * Gunshot wound	2 (0.2%) * Cardiac failure congestive * Sudden death in subject with multiple comorbidities (not related to COVID-19)	0	0

FIG. 71

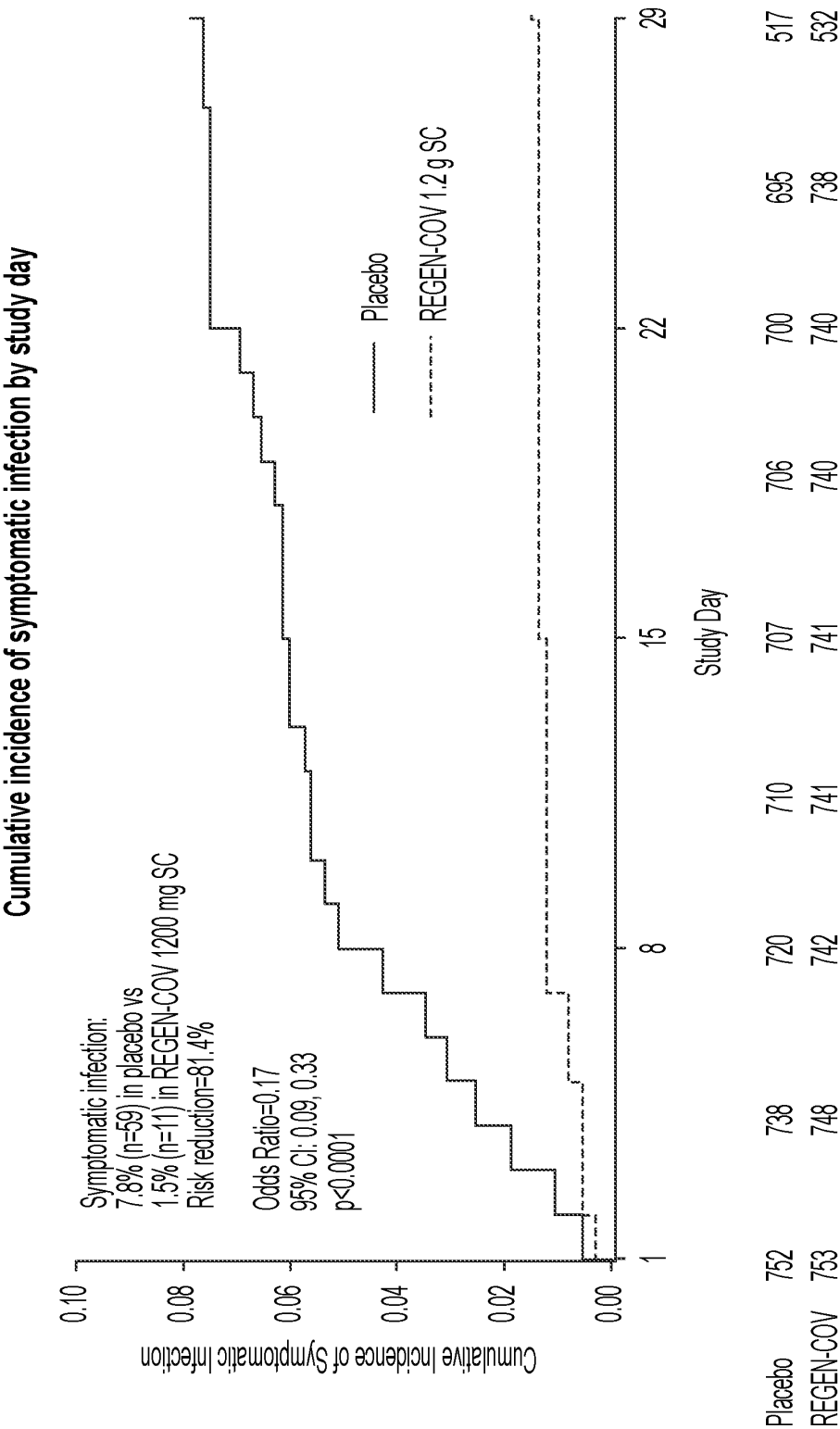


FIG. 72

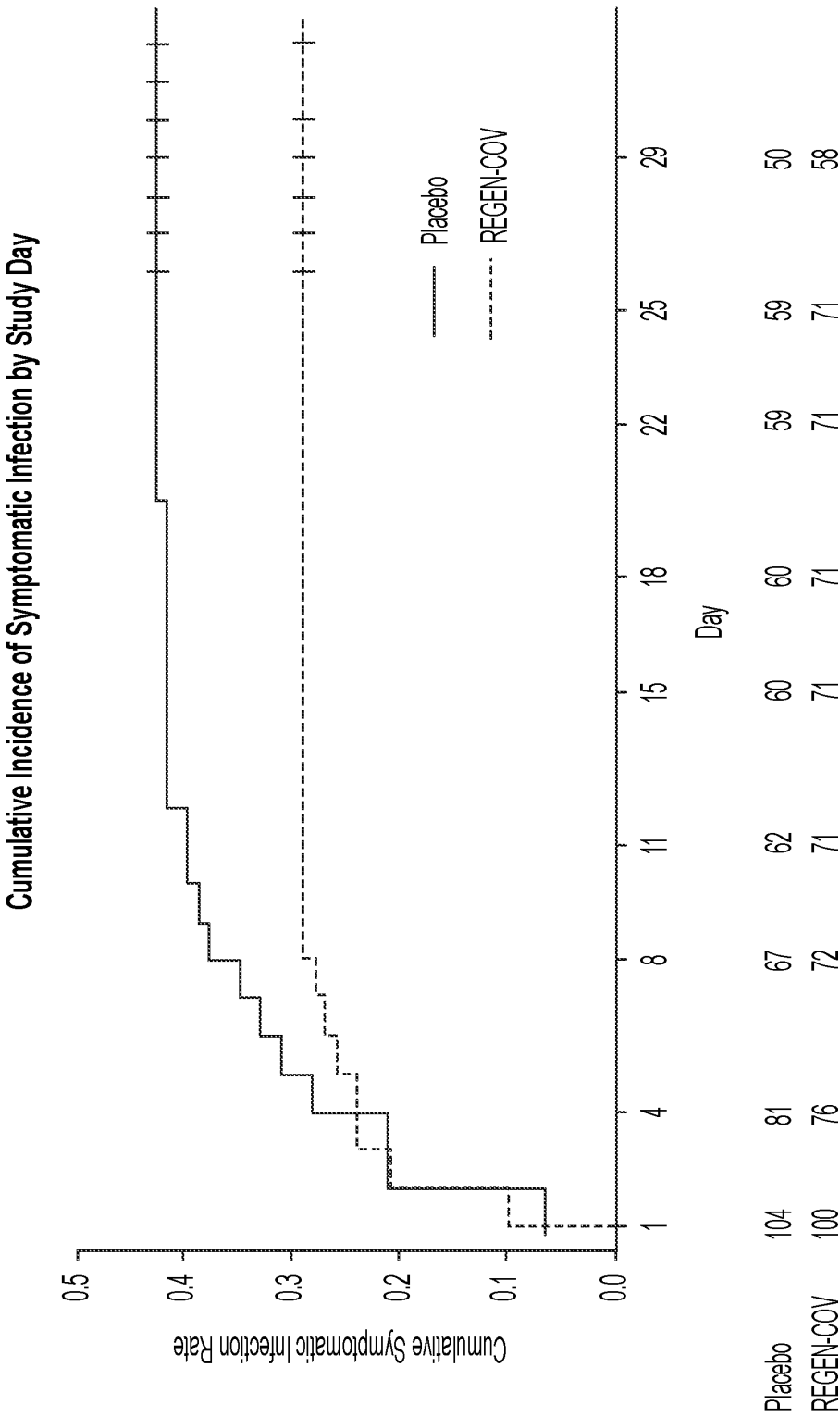
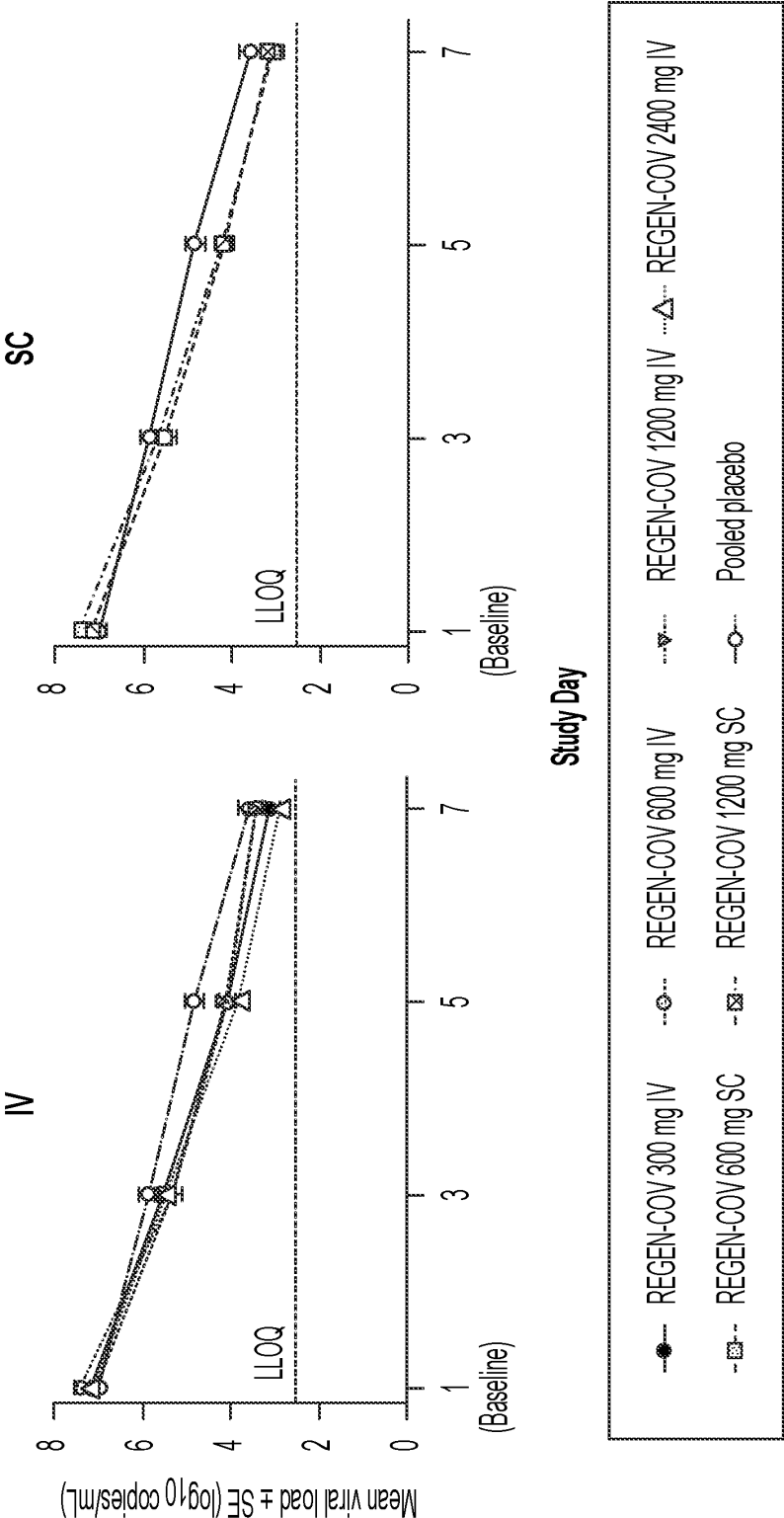


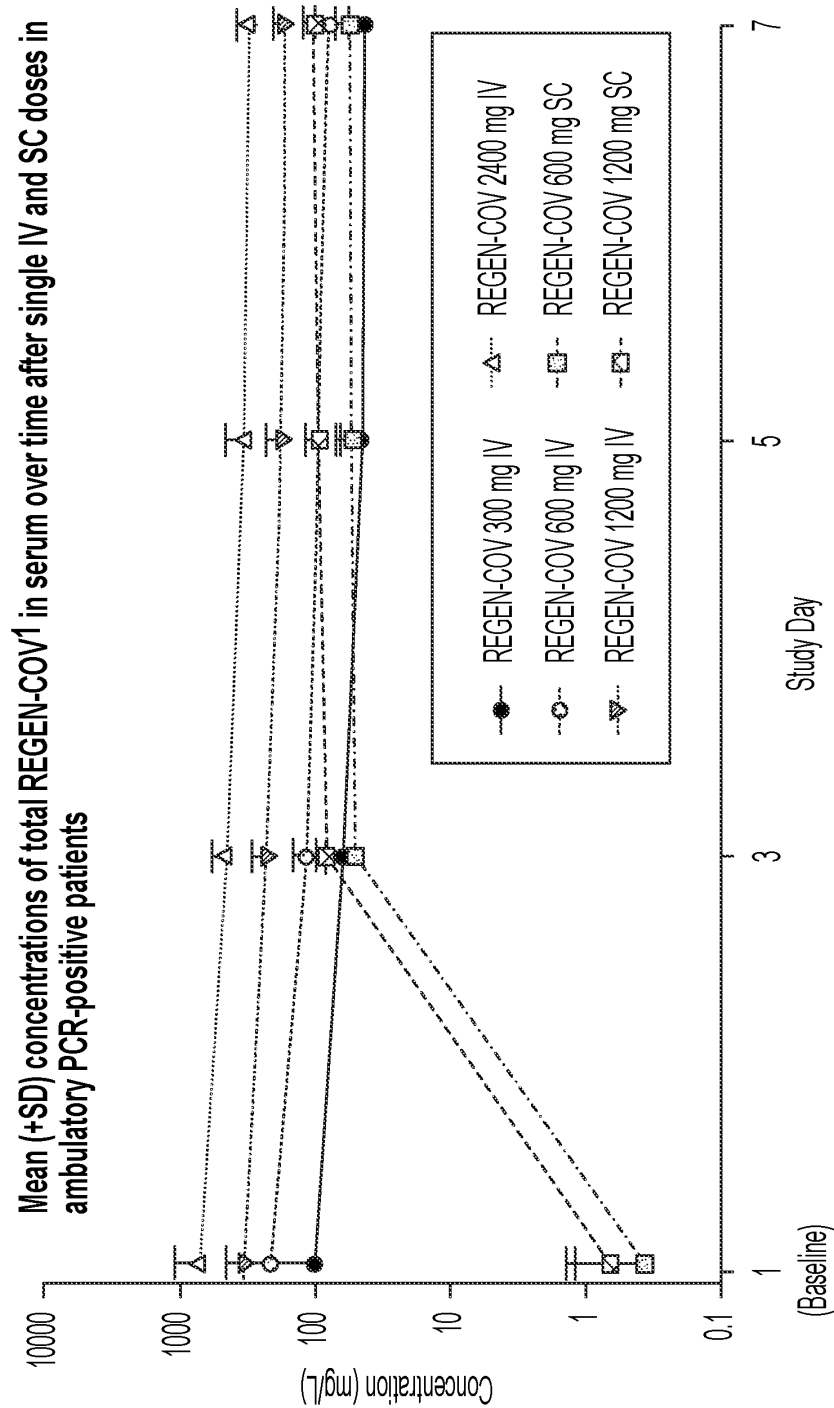
FIG. 73

Mean viral load (log₁₀ copies/mL) over time in patients PCR-positive and seronegative at baseline



IV, intravenous; LLOQ, lower limit of quantification; SC, subcutaneous; SE, standard error.

FIG. 74



¹Represents the total monoclonal antibody concentration, calculated as the sum of casirivimab and imdevimab concentrations at each time point. IV, intravenous; SC, subcutaneous; SD, standard deviation.

FIG. 75

108/153

Screening, Randomization, Treatment, and Analysis

* In the original phase 3 portion of the trial, Regeneron requested that 2, 1, and 5 patients in the placebo, 2400 mg, and 8000 mg groups, respectively, withdraw from the trial as these patients did not meet the inclusion/exclusion criteria (ie, were randomized in error).

† In the amended phase 3 portion of the trial, Regeneron requested that 2, 4, and 2 patients in the placebo, 1200 mg, and 2400 mg groups, respectively, withdraw from the trial as these patients did not meet the inclusion/exclusion criteria (ie, were randomized in error).

IV, intravenous; mFAS, modified full analysis set, RF, risk factor.

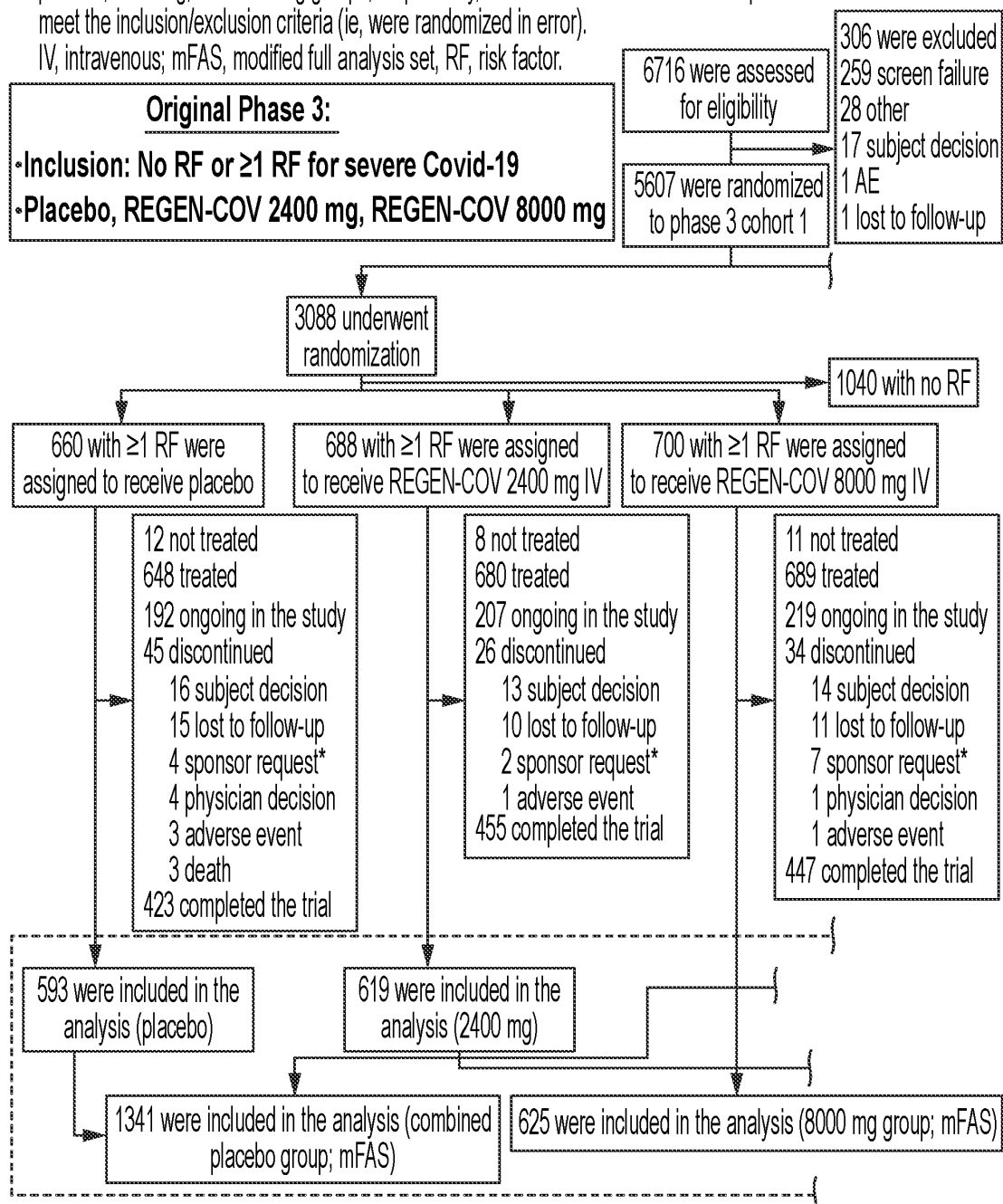


FIG. 76

109/153

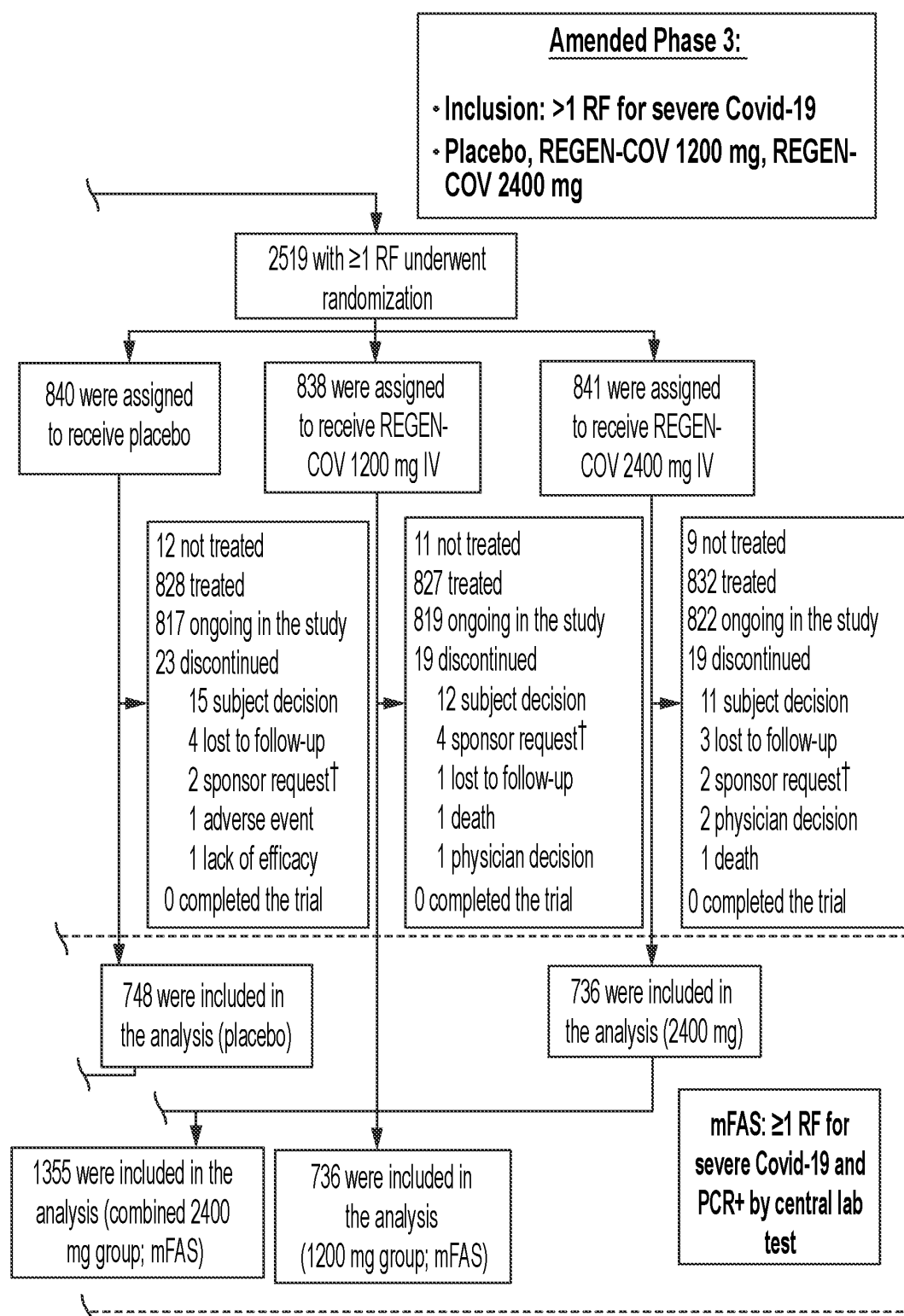
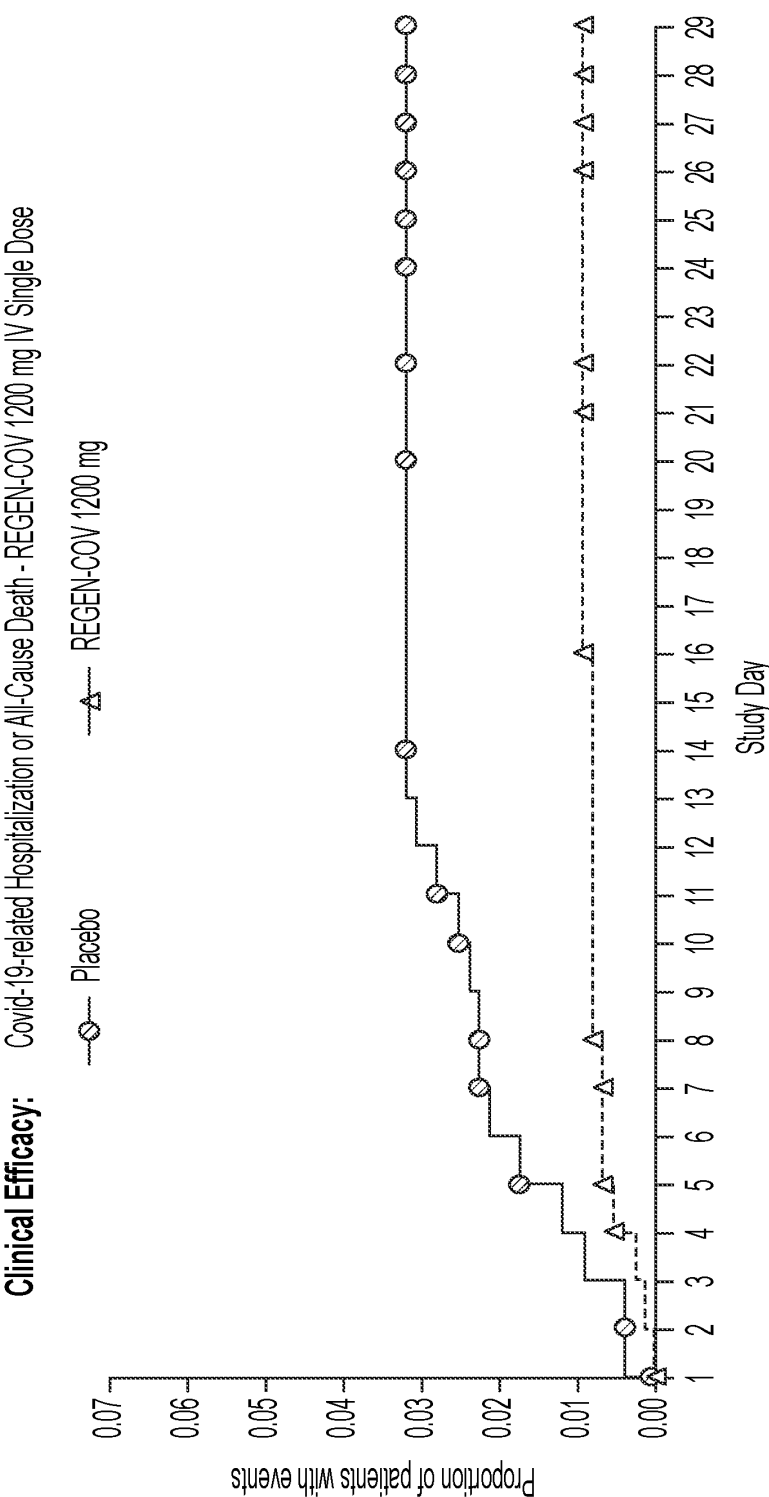


FIG. 76 (Cont.)



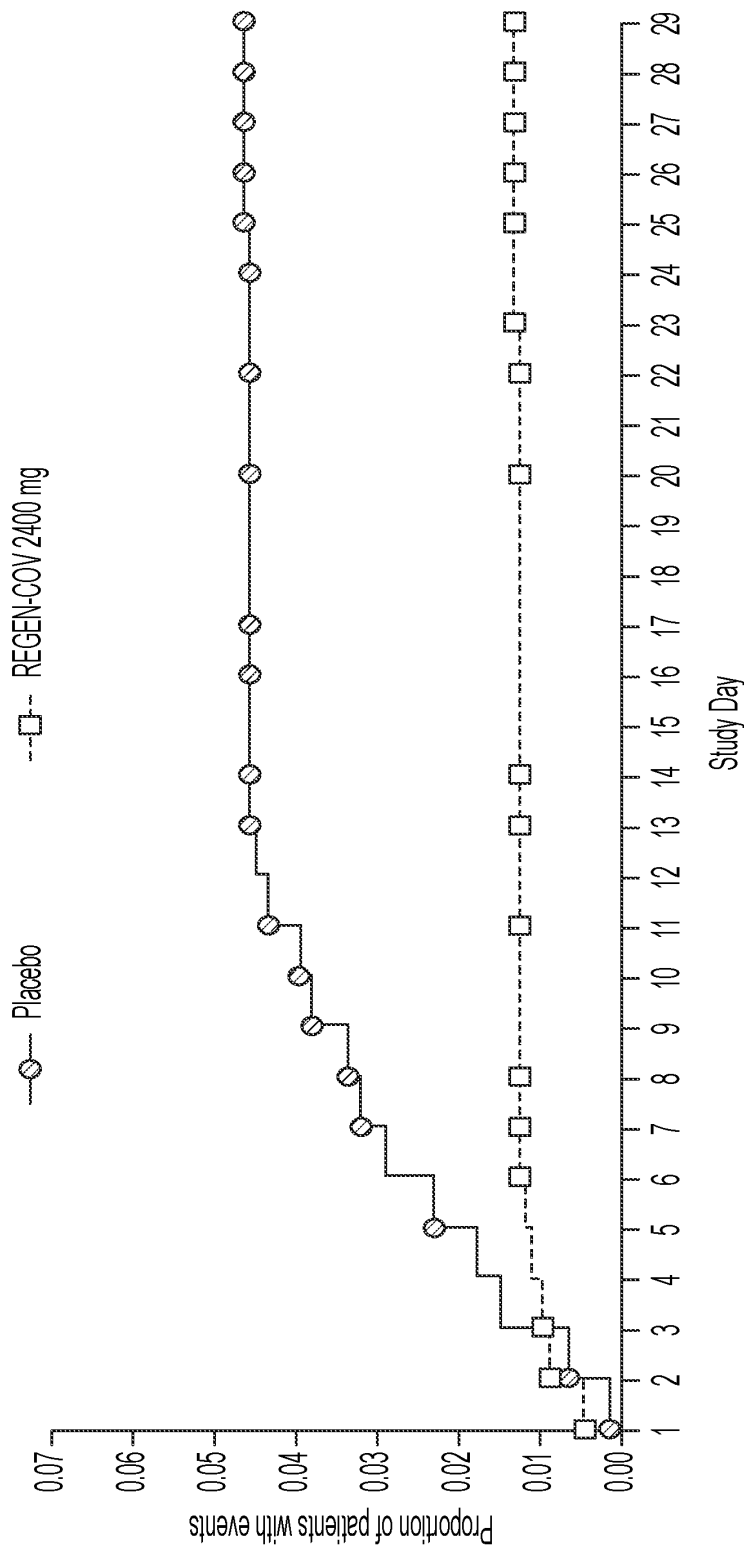
Placebo 748 748 744 740 738 733 730 728 727 726 724 720 718 717 716 716 716 716 716 715 715 702 701 699 690 669 598

REGEN-COV 736 734 733 732 728 726 726 723 723 723 723 723 723 723 721 721 721 720 708 708 703 695 624

1200 mg

FIG. 77A

Clinical Efficacy: Covid-19-related Hospitalization or All-Cause Death - REGEN-COV 2400 mg IV Single Dose



Placebo 1341 1338 1330 1319 1315 1306 1298 1291 1287 1275 1267 1265 1263 1260 1259 1258 1258 1257 1257 1242 1242 1241 1238 1211 1170 1052
REGEN-COV 1355 1346 1339 1337 1335 1334 1332 1330 1329 1329 1329 1327 1327 1326 1324 1324 1324 1324 1324 1323 1323 1316 1314 1314 1292 1247 1113
2400 mg

FIG. 77B

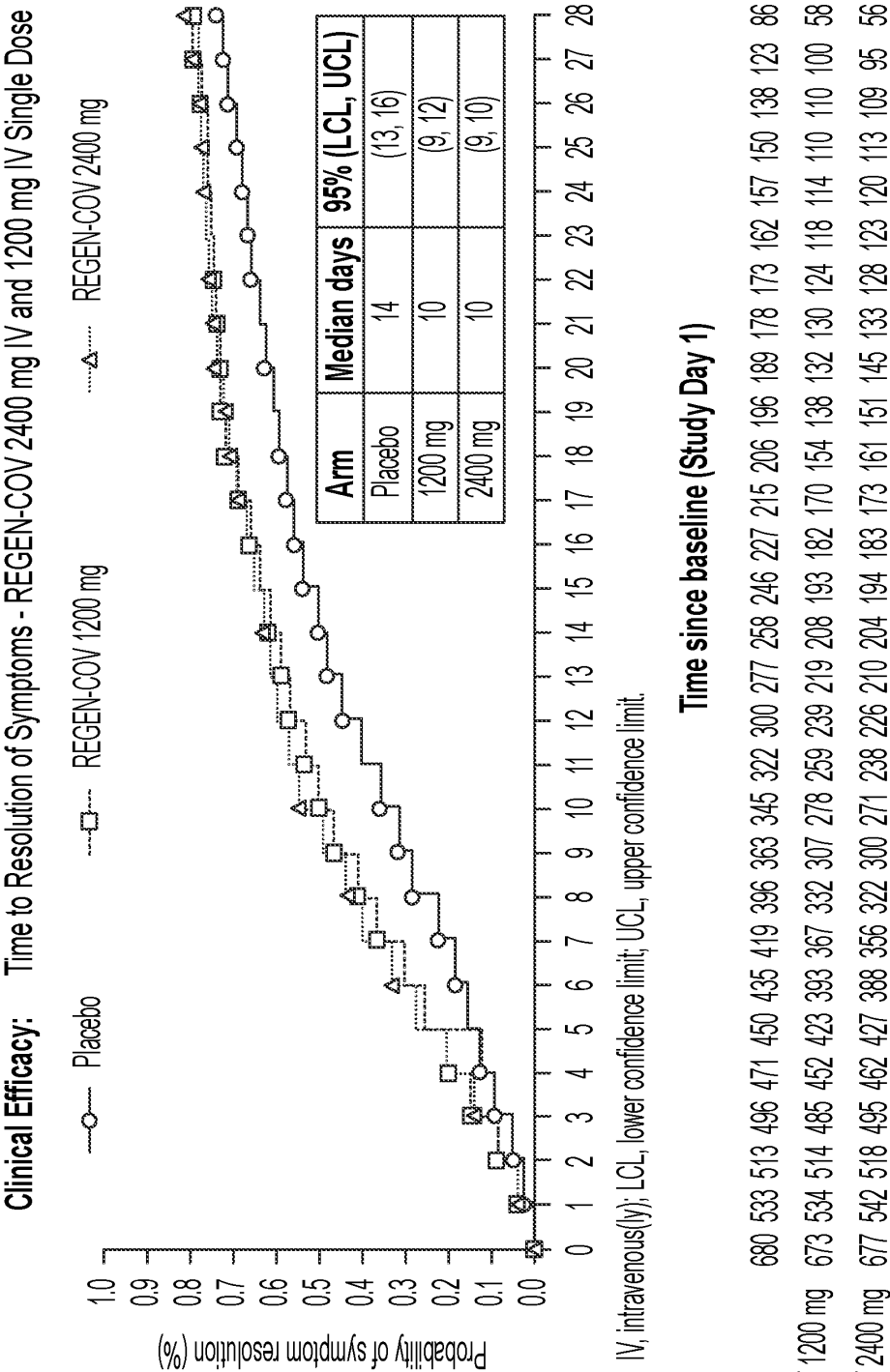


FIG. 77C

Demographic and Baseline Medical Characteristics* (mFAS)

Characteristic	REGEN-COV 2400 mg (n=1355)	Placebo (2400 mg) (concurrent) (n=1341)	REGEN-COV 1200 mg (n=736)	Placebo (1200 mg) (concurrent) (n=748)	Total (n=4057)
Demographics					
Median age (IQR) — year	50.0 (39.0–60.0)	50.0 (37.0–58.0)	48.5 (37.0–57.5)	48.0 (35.0–57.0)	50.0 (38.0–59.0)
Baseline age category — no. (%)					
Age ≤50 years	715 (52.8)	678 (50.6)	357 (48.5)	356 (47.6)	2101 (51.8)
Age ≥65 years	214 (15.8)	144 (10.7)	93 (12.6)	88 (11.8)	548 (13.5)
Male sex — no. (%)	656 (48.4)	633 (47.2)	364 (49.5)	352 (47.1)	1977 (48.7)
Hispanic or Latino ethnic group — no. (%)†	464 (34.2)	471 (35.1)	312 (42.4)	295 (39.4)	1424 (35.1)
Race — no. (%)†					
White	1161 (85.7)	1136 (84.7)	595 (80.8)	611 (81.7)	3426 (84.4)
Black or African American	67 (4.9)	66 (4.9)	38 (5.2)	38 (5.1)	204 (5.0)
Asian	52 (3.8)	56 (4.2)	38 (5.2)	36 (4.8)	172 (4.2)
American Indian or Alaska Native	19 (1.4)	13 (1.0)	17 (2.3)	10 (1.3)	52 (1.3)

FIG. 78

Unknown	28 (2.1)	43 (3.2)	36 (4.9)	37 (4.9)	122 (3.0)
Not reported	24 (1.8)	26 (1.9)	10 (1.4)	15 (2.0)	74 (1.8)
Median weight (IQR) — kg	87.50 (75.15–102.10)	87.90 (74.30–103.00)	86.20 (74.40–102.10)	86.20 (72.80–102.40)	87.80 (74.80–103.00)
Body-mass index†	31.09±6.331	31.19±6.630	31.54±7.309	31.07±6.457	31.33±6.761
Obesity — no. (%) §	787 (58.1)	772 (57.6)	410 (55.7)	427 (57.1)	2353 (58.0)
At least one risk factor for severe Covid-19 — no. (%)¶	1355 (100)	1341 (100)	736 (100)	748 (100)	4057 (100)
Medical/Clinical Characteristics					
Positive baseline qualitative RT-PCR — no. (%)	1353 (99.9)	1333 (99.4)	734 (99.7)	744 (99.5)	4045 (99.7)
Baseline viral load in nasopharyngeal swab (raw values)					
No. of patients	1353	1333	734	744	4045
Mean viral load — (10 ⁶) copies/ml	250.74±764.3	293.65±1061.1	439.04±1703.6	372.54±1300.5	286.58±1070.8
Median viral load (range) — (10 ⁶) copies/ml	10.30 (0–10600)	9.01 (0–16100)	8.37 (0–29700)	7.12 (0–16100)	9.55 (0–29700)
Baseline viral load in nasopharyngeal swab (log ₁₀ scale)					
No. of patients	1353	1333	734	744	4045

FIG. 78 (Cont.)

Mean viral load — log ₁₀ copies/ml	6.72±1.707	6.66±1.754	6.73±1.863	6.63±1.823	6.69±1.746
Median viral load (range) — log ₁₀ copies/ml	7.01 (2.6–10.0)	6.95 (2.6–10.2)	6.92 (2.6–10.5)	6.85 (2.6–10.2)	6.98 (2.6–10.5)
Baseline serum C-reactive protein level					
No. of patients	1242	1243	713	724	3742
Mean level — mg/l	11.992±23.2378	12.971±24.5365	13.244±23.7685	13.097±24.9732	12.877±24.5170
Median level (range) — mg/l	4.615 (0.11–354.16)	4.940 (0.10–242.73)	4.910 (0.11–238.53)	4.865 (0.16–227.45)	4.850 (0.10–354.16)
Baseline serum antibody status — no. (%)					
Negative	940 (69.4)	930 (69.4)	500 (67.9)	519 (69.4)	2782 (68.6)
Positive	323 (23.8)	297 (22.1)	177 (24.0)	164 (21.9)	959 (23.6)
Other	92 (6.8)	114 (8.5)	59 (8.0)	65 (8.7)	316 (7.8)
Median time from symptom onset to randomization (IQR) — days	3.0 (2–5)	3.0 (2–5)	3.0 (2–5)	3.0 (2–4)	3.0 (2–5)

*Plus—minus values are means ±SD. Percentage may not total 100 because of rounding. IQR denotes interquartile range, RT-PCR reverse-transcriptase polymerase chain reaction, and SD standard deviation.

† Race and ethnic group were reported by the patients.

‡ The body-mass index is the weight in kilograms divided by the square of the height in meters.

§ Obesity is defined as a body-mass index of greater than or equal to 30.

¶ Risk factors for hospitalization include an age of more than 50 years, obesity, cardiovascular disease (including hypertension), chronic lung disease (including asthma), chronic metabolic disease (including diabetes), chronic kidney disease (including receipt of dialysis), chronic liver disease, and immunocompromised (immunosuppression or receipt of immunosuppressants).

FIG. 78 (Cont.)

Hierarchical End Points

Hypothesis Testing Hierarchy*	Comparison	Treatment Effect	P value
1. Proportion of patients with ≥ 1 Covid-19-related hospitalization or all-cause death through day 29	2400 mg vs placebo	18/1355 (1.3%) vs 62/1341 (4.6%); 71.3% reduction (95% CI: 51.7%, 82.9%)	<0.0001
2. Proportion of patients with ≥ 1 Covid-19-related hospitalization or all-cause death through day 29	1200 mg vs placebo	7/736 (1.0%) vs 24/748 (3.2%); 70.4% reduction (95% CI: 31.6%, 87.1%)	0.0024
3. Proportion of patients with ≥ 1 Covid-19-related hospitalization or all-cause death through day 29 in patients with baseline viral load $>10^6$ copies/mL	2400 mg vs placebo	13/924 (1.4%) vs 55/876 (6.3%); 77.6% reduction (95% CI: 59.3%, 87.7%)	<0.0001
4. Proportion of patients with ≥ 1 Covid-19-related hospitalization or all-cause death through day 29 in patients who are serum antibody negative at baseline	2400 mg vs placebo	12/940 (1.3%) vs 49/930 (5.3%); 75.8% reduction (95% CI: 54.7%, 87.0%)	<0.0001
5. Proportion of patients with ≥ 1 Covid-19-related hospitalization or all-cause death through day 29 in patients with baseline viral load $>10^6$ copies/mL	1200 mg vs placebo	6/482 (1.2%) vs 20/471 (4.2%); 70.7% reduction (95% CI: 27.6%, 88.1%)	0.0045
6. Proportion of patients with ≥ 1 Covid-19-related hospitalization or all-cause death through day 29 in patients who are serum antibody negative at baseline	1200 mg vs placebo	3/500 (0.6%) vs 18/519 (3.5%); 82.7% reduction (95% CI: 41.6%, 94.9%)	0.0014
7. Proportion of patients with ≥ 1 Covid-19-related hospitalization or all-cause death from day 4 through day 29	2400 mg vs placebo	5/1351 (0.4%) vs 46/1340 (3.4%); 89.2% reduction (95% CI: 73.0%, 95.7%)	<0.0001
8. Proportion of patients with ≥ 1 Covid-19-related hospitalization or all-cause death from day 4 through day 29	1200 mg vs placebo	5/735 (0.7%) vs 18/748 (2.4%); 71.7% reduction (95% CI: 24.3%, 89.4%)	0.0101

FIG. 79

9. Time to Covid-19 symptoms resolution	2400 mg vs placebo	Median 10 vs 14 days; 4-day faster resolution	<0.0001
10. Time to Covid-19 symptoms resolution	1200 mg vs placebo	Median 10 vs 14 days; 4-day faster resolution	<0.0001

* All analyses in mFAS: all randomized patients with a positive SARS-CoV-2 RT-qPCR test from nasopharyngeal swabs at randomization and ≥ 1 risk factor for severe COVID-19.

CI, confidence interval; mFAS, modified full analysis set; RT-qPCR, reverse transcriptase quantitative polymerase chain reaction.

FIG. 79 (Cont.)

Overview of Serious Adverse Events and Adverse Events of Special Interest in the Safety Population

Event	Placebo (n=1843)	REGEN-COV 1200 mg IV (n=827)	REGEN-COV 2400 mg IV (n=1849)	REGEN-COV 8000 mg IV (n=1012)	Total (n=5531)
<i>no. of patients (percent)</i>					
Serious adverse event					
Any serious adverse event	74 (4.0)	9 (1.1)	24 (1.3)	17 (1.7)	124 (2.2)
Any serious adverse event of special interest*	6 (0.3)	1 (0.1)	1 (<0.1)	1 (<0.1)	9 (0.2)
Adverse events of special interest that occurred or worsened during the observation period†					
Grade ≥2 infusion-related reaction within 4 days	0	2 (0.2)	1 (<0.1)	3 (0.3)	6 (0.1)
Grade ≥2 hypersensitivity reaction within 29 days	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)
Adverse events that occurred or worsened during the observation period†					
Patients with event	189 (10.3)	59 (7.1)	142 (7.7)	85 (8.4)	475 (8.6)
Patients with grade 3 or 4 event	62 (3.4)	11 (1.3)	18 (1.0)	15 (1.5)	106 (1.9)
Patients with event that led to death	5 (0.3)	1 (0.1)	1 (<0.1)	0	7 (0.1)
Patients with event that led to withdrawal from the trial	1 (<0.1)	0	1 (<0.1)	2 (0.2)	4 (<0.1)
Patients with event that led to infusion interruption*	0	1 (0.1)	0	1 (<0.1)	2 (<0.1)

* Events were hypersensitivity reactions (grade ≥2), infusion-related reactions (grade ≥2), or medically-attended visits, regardless of relation to Covid-19.

† Events listed here were not present at baseline or were an exacerbation of a preexisting condition that occurred during the observation period, which is defined as the time from administration of REGEN-COV or placebo to the final follow-up visit.

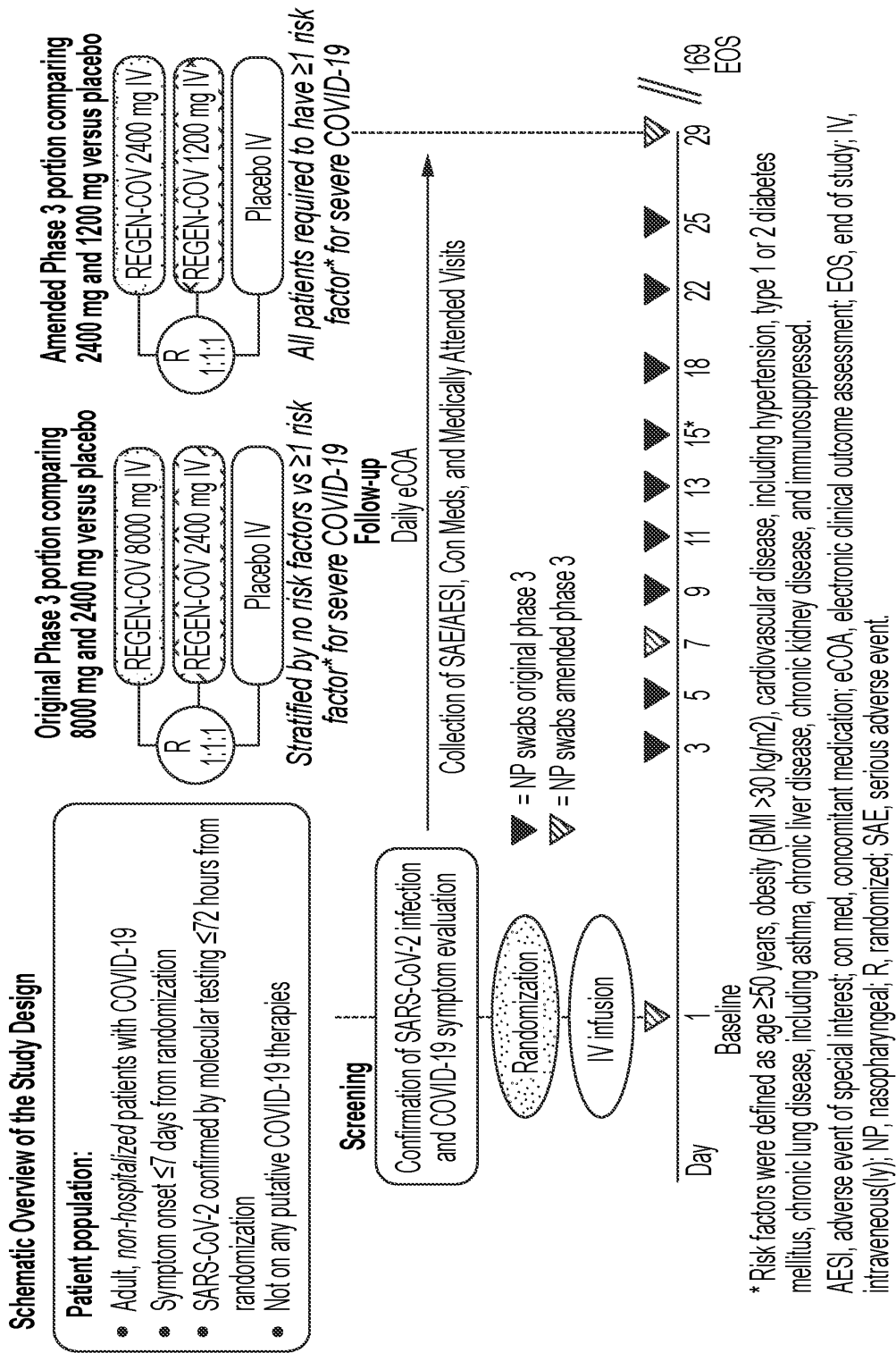


FIG. 81

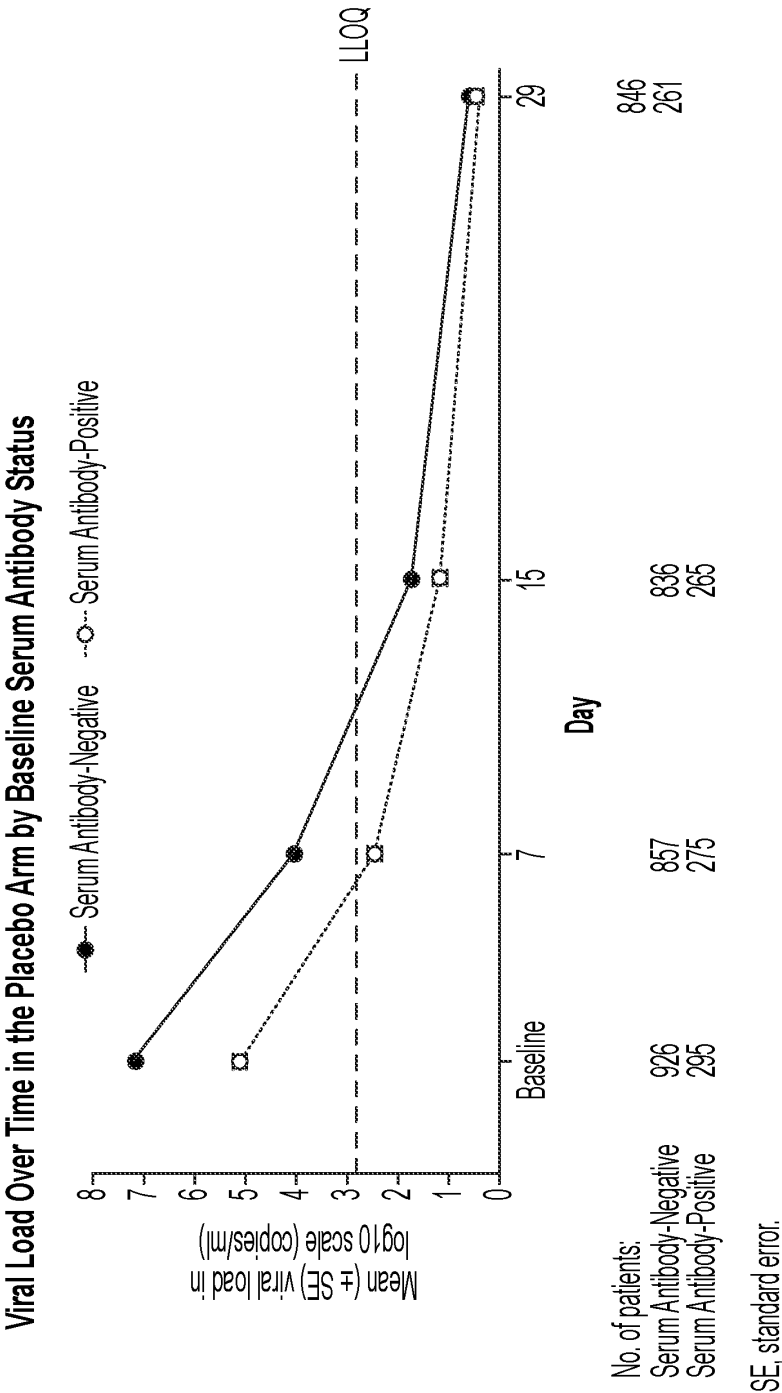


FIG. 82

Forest Plots: COVID-19-related Hospitalization or All-Cause Death Through Day 29
Subgroups: Baseline viral load and serum antibody status

COVID-19 Related Hospitalizations or All-Cause Deaths through Day 29
in Outpatients with 1 or more Risk Factors for Severe COVID-19

Phase 3 Study COV-2067

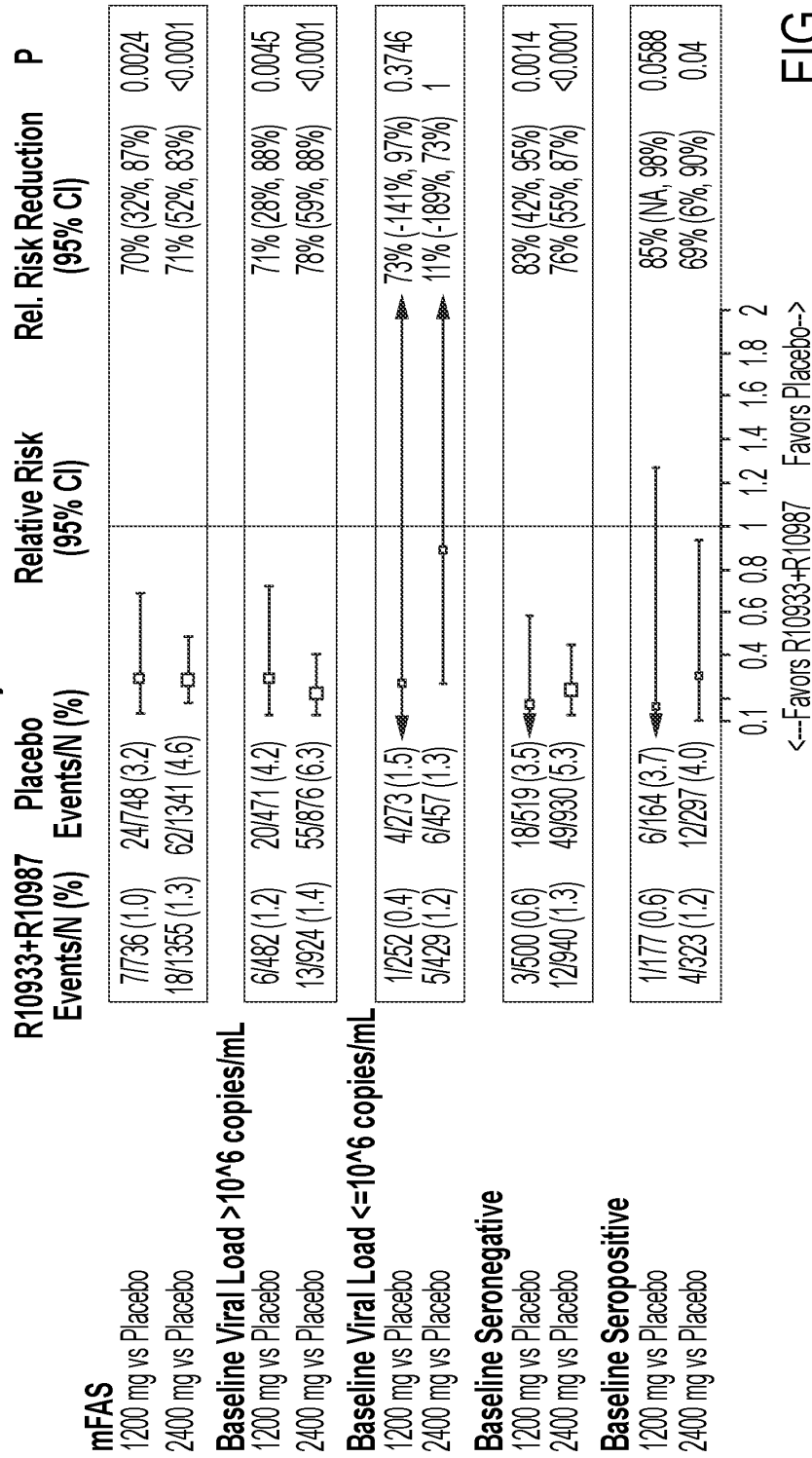


FIG. 83A

122/153

Subgroups: Protocol-defined risk factors

COVID-19 Related Hospitalizations or All-Cause Deaths through Day 29 in Outpatients
Across Risk Factor Subgroups for Severe COVID-19
Phase 3 Study COV-2067

Risk Factor (Sub) Group	Casirivimab+Imdevimab Events/N (%)	Placebo Events/N (%)	Relative Risk (95% CI)	Rel. Risk Reduction P (95% CI)
>=1 protocol-defined risk factor for severe COVID-19				
1200 mg vs Placebo	7/736 (1.0)	24/748 (3.2)		0.0024
2400 mg vs Placebo	18/1355 (1.3)	62/1341 (4.6)		<0.0001
Age >= 50 years				
1200 mg vs Placebo	7/357 (2.0)	19/356 (5.3)		0.0166
2400 mg vs Placebo	15/715 (2.1)	52/678 (7.7)		<0.0001
Obesity (BMI >= 30 kg/m^2)				
1200 mg vs Placebo	2/410 (0.5)	15/427 (3.5)		0.0022
2400 mg vs Placebo	13/787 (1.7)	38/772 (4.9)		0.0003
Cardiovascular disease, including hypertension				
1200 mg vs Placebo	5/282 (1.8)	15/266 (5.6)		0.0211
2400 mg vs Placebo	7/520 (1.3)	40/473 (8.5)		<0.0001
Chronic metabolic disease, including diabetes				
1200 mg vs Placebo	2/94 (2.1)	6/100 (6.0)		0.2807
2400 mg vs Placebo	8/202 (4.0)	17/210 (8.1)		0.0842

FIG. 83B

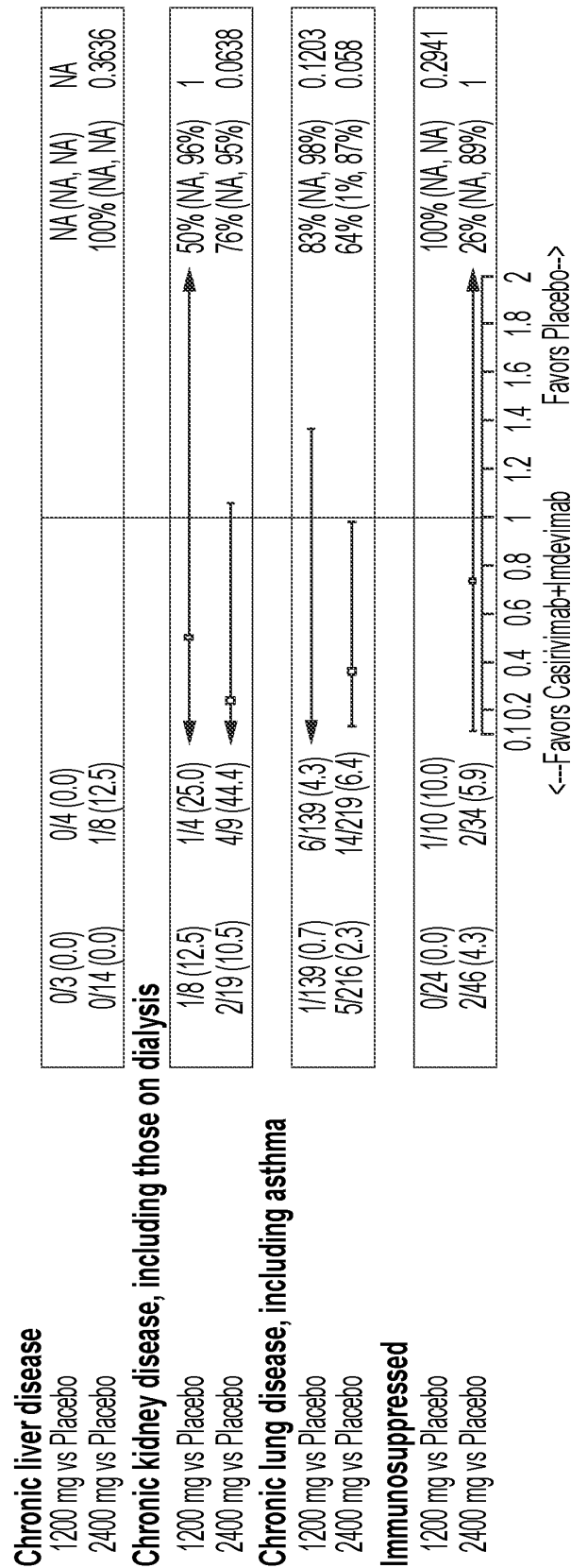


FIG. 83B (Cont.)

Subgroups: Other risk factor combinations

COVID-19 Related Hospitalizations or All-Cause Deaths through Day 29 in Outpatients
Across Risk Factor Subgroups for Severe COVID-19
Phase 3 Study COV-2067

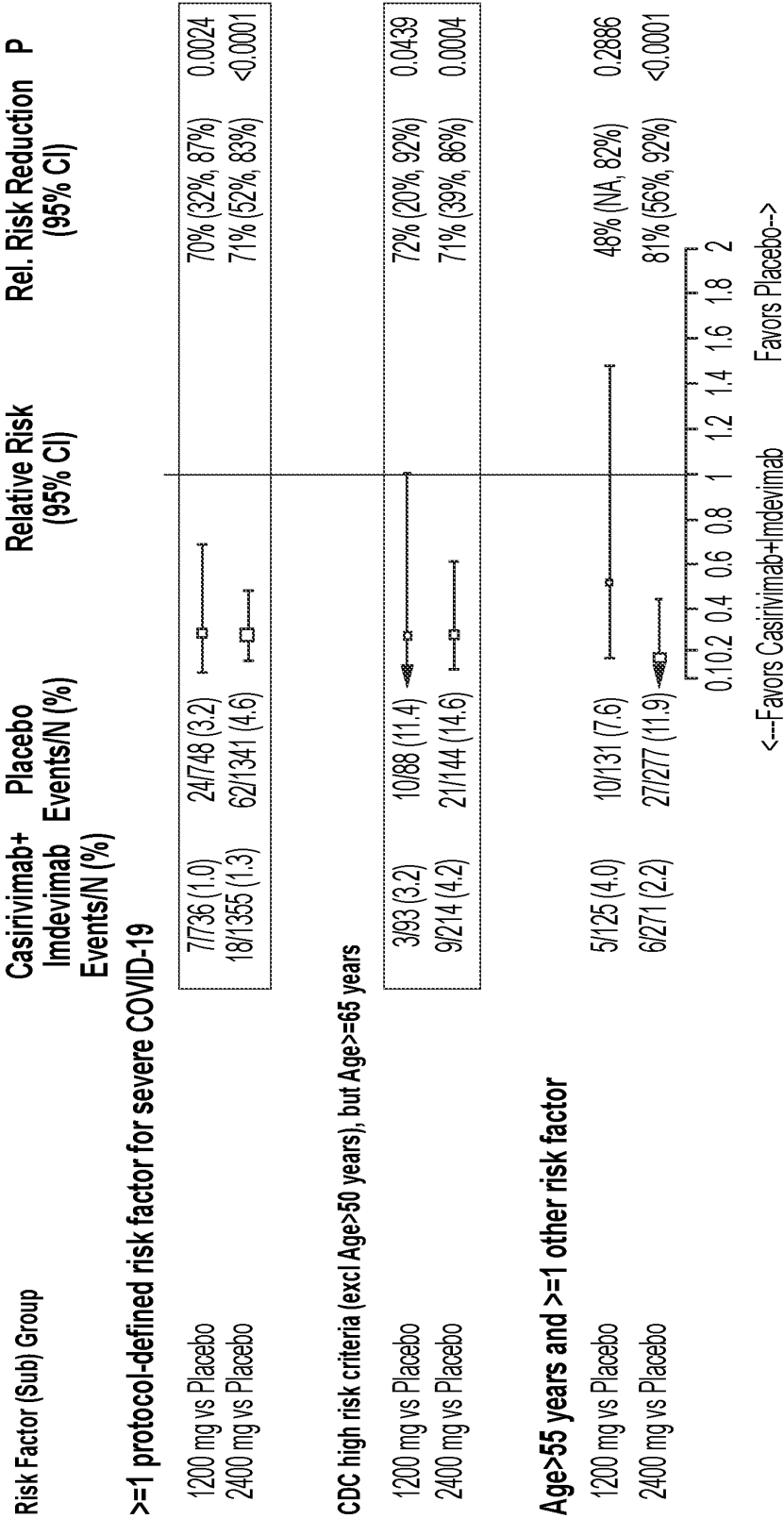


FIG. 83C

COVID-19-related Hospitalization or All-Cause Death - Day 4 through Day 29

A. COVID-19-related hospitalization or all-cause death - Day 4 through Day 29 - REGEN-COV 1200 mg IV single dose

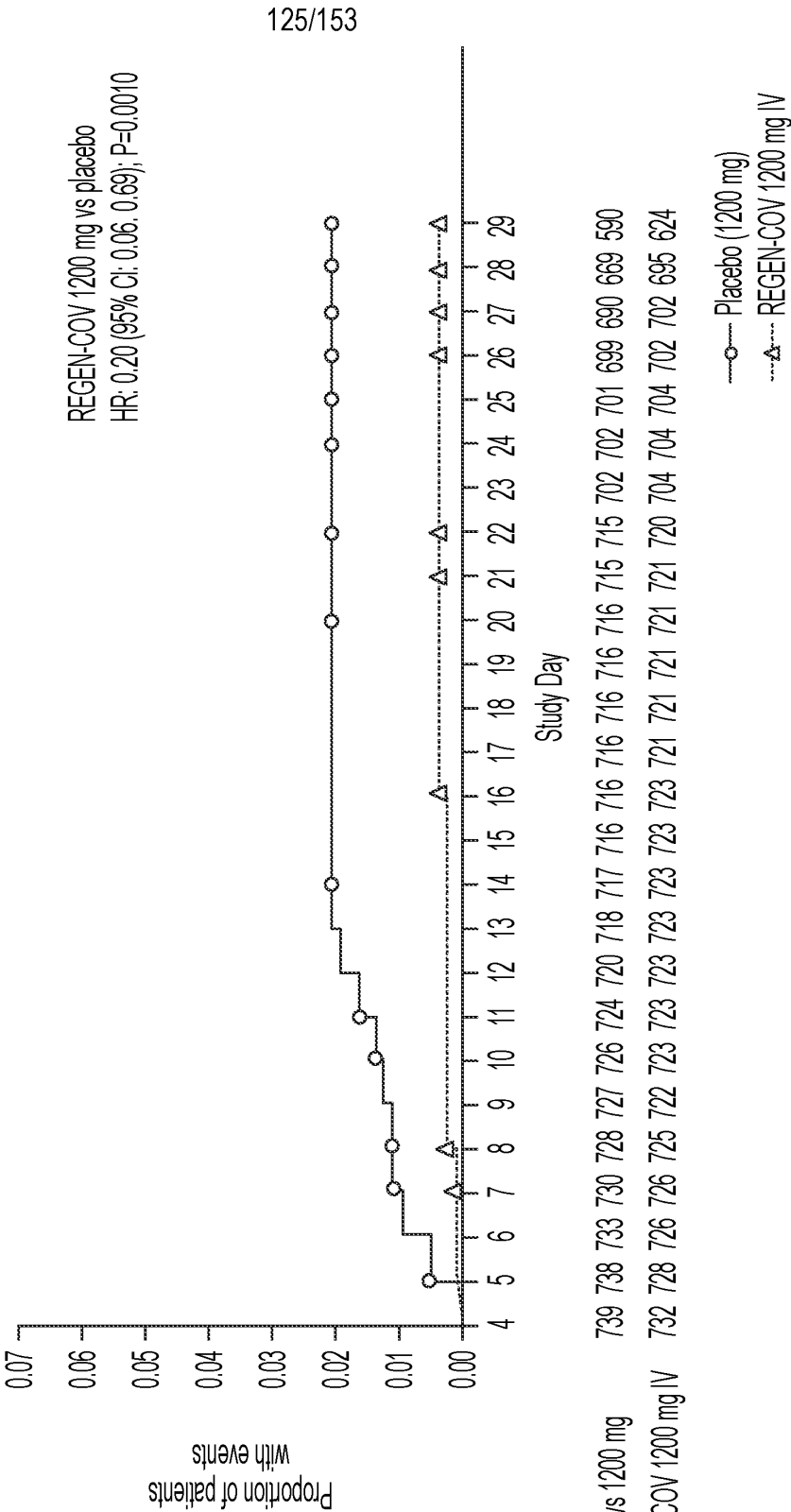


FIG. 84A

B. COVID-19-related hospitalization or all-cause death - Day 4 through Day 29 - REGEN-COV 2400 mg IV single dose

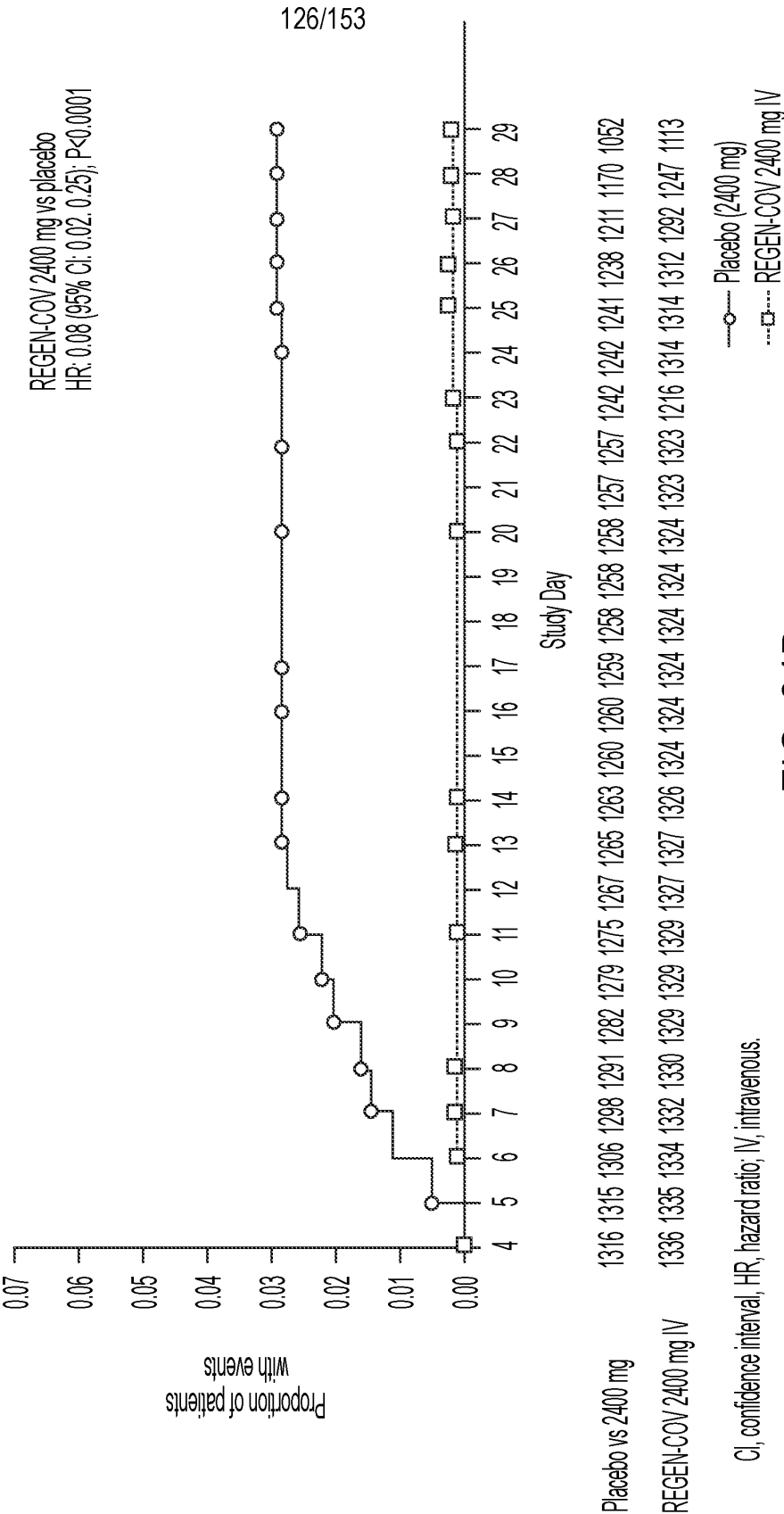


FIG. 84B

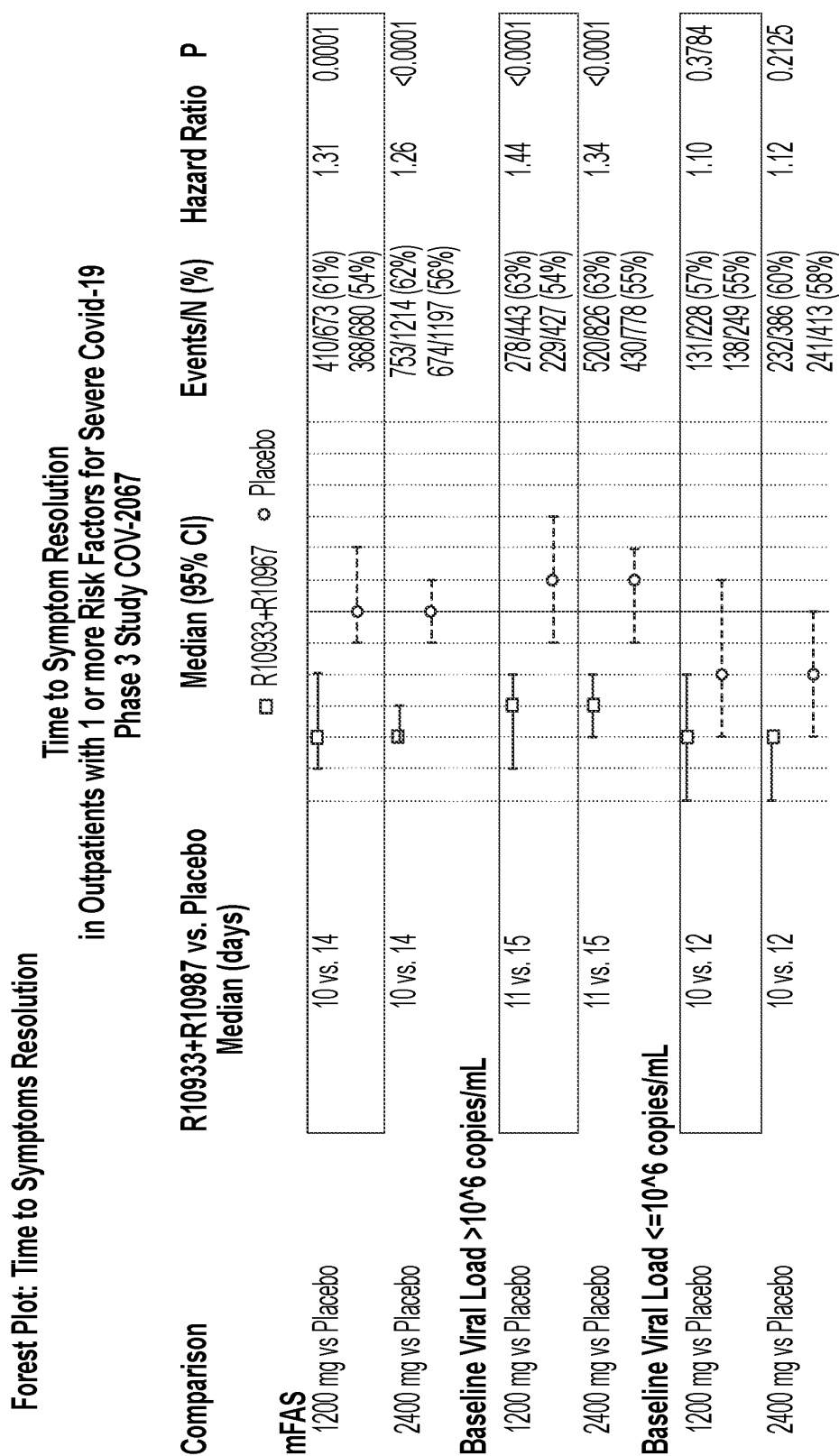


FIG. 85

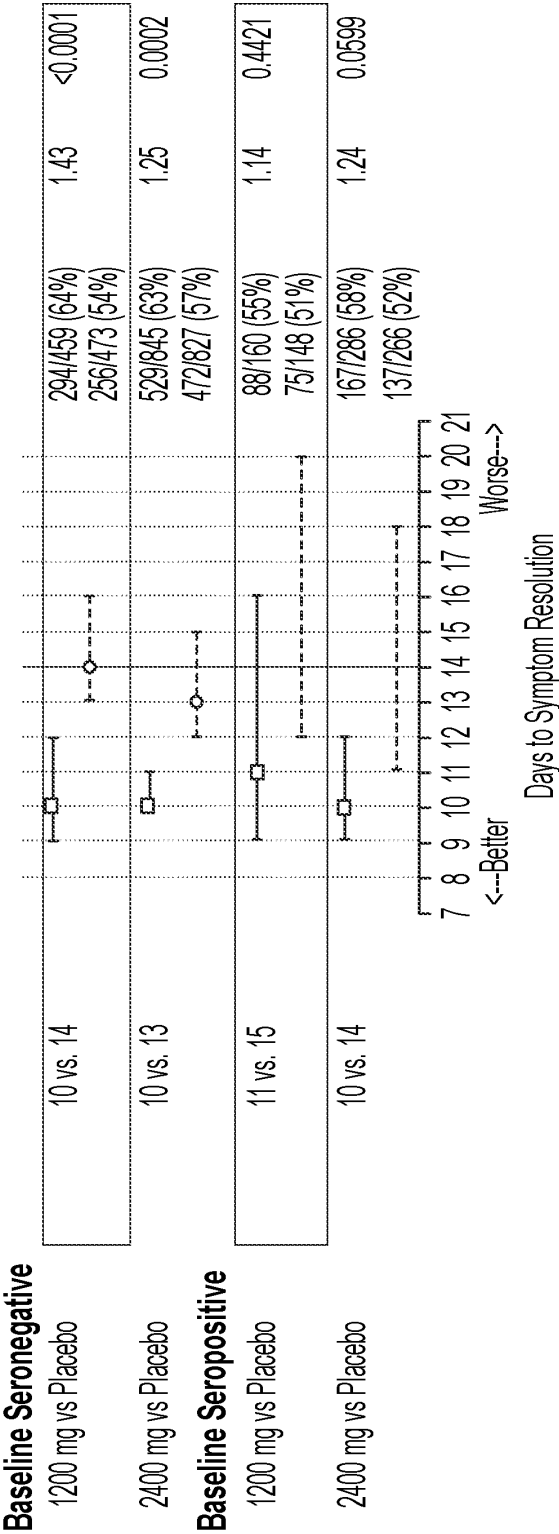


FIG. 85 (Cont.)

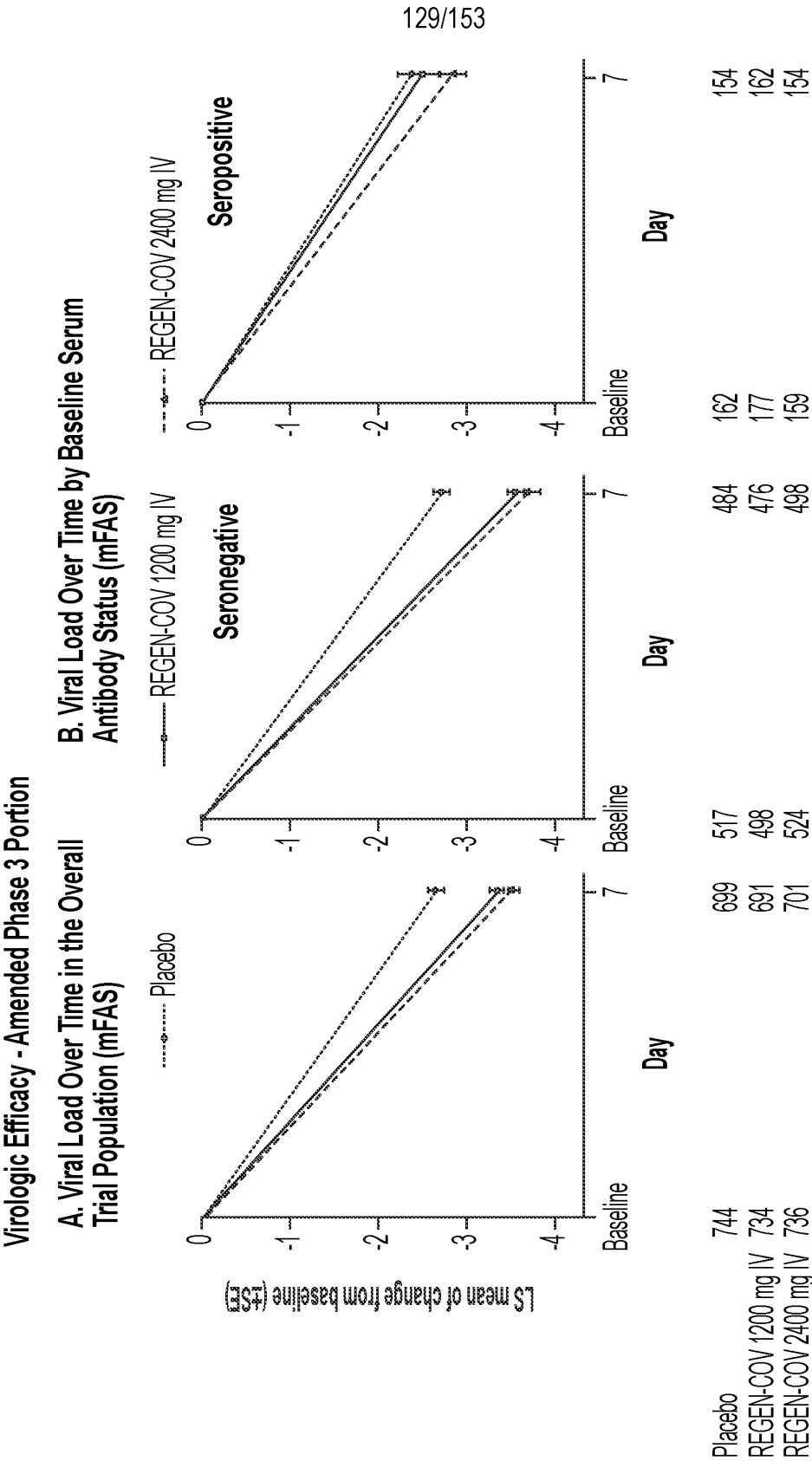
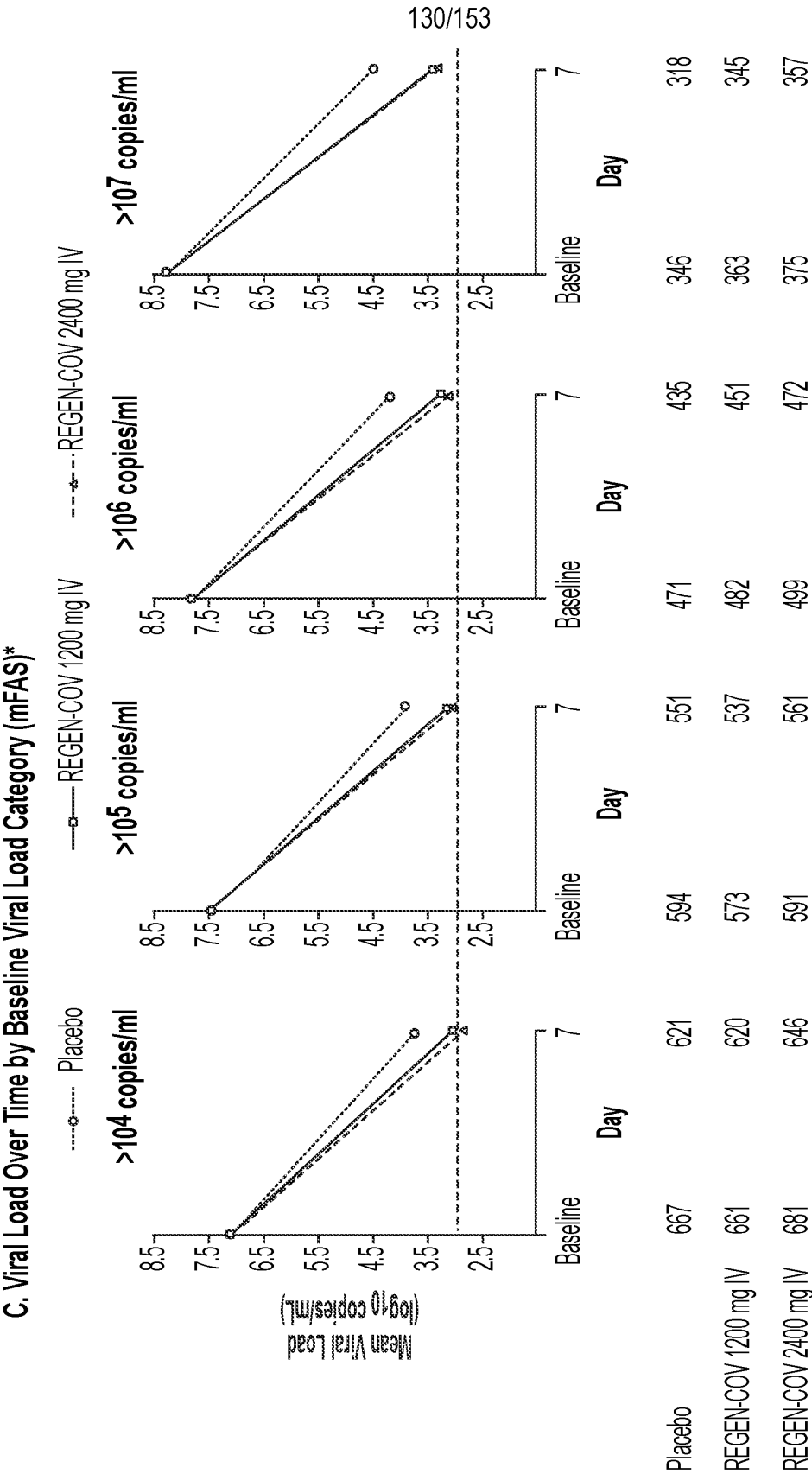


FIG. 86A

FIG. 86B



* The lower limit of detection (dashed line) is 714 copies per milliliter (2.85 log₁₀ copies per milliliter). mFAS, modified full analysis set; IV, intravenous, SE, standard error.

FIG. 86C

Forest Plot: Virologic Efficacy - Amended Phase 3 Portion

Change from Baseline in Viral Load (log₁₀ copies/mL) at Day 7
In Outpatients with 1 or more Risk Factors for Severe COVID-19
Phase 3 Study COV-2067

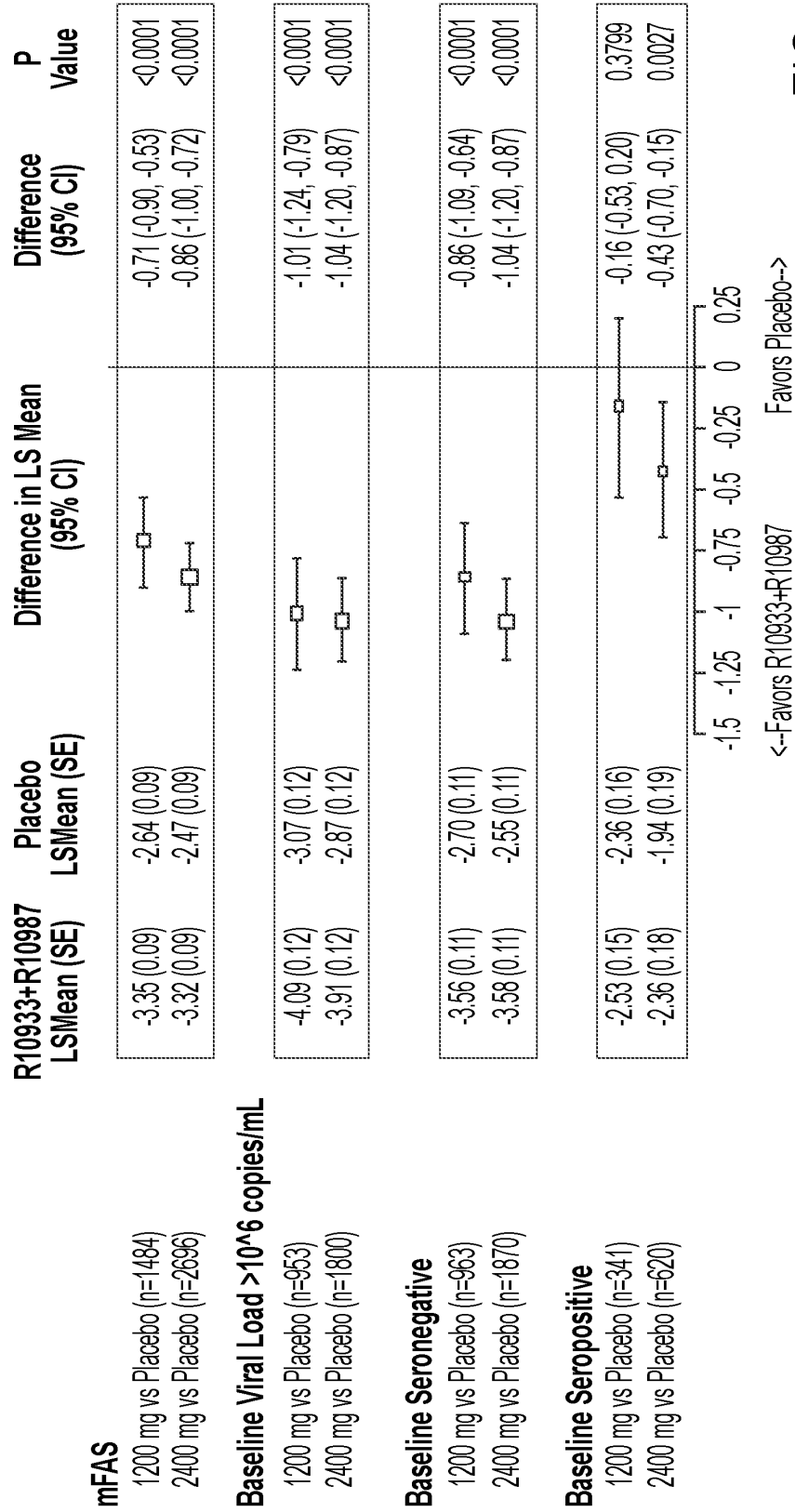


FIG. 87

Virologic Efficacy - Original Phase 3 Portion

A. Viral Load Over Time in the Overall Trial Population (mFAS)

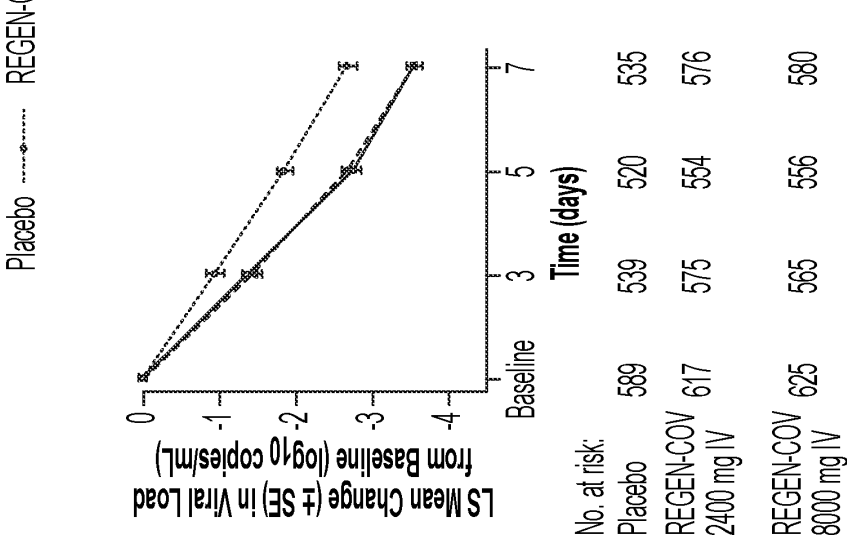


FIG. 88A

B. Viral Load Over Time by Baseline Serum Antibody Status (mFAS)

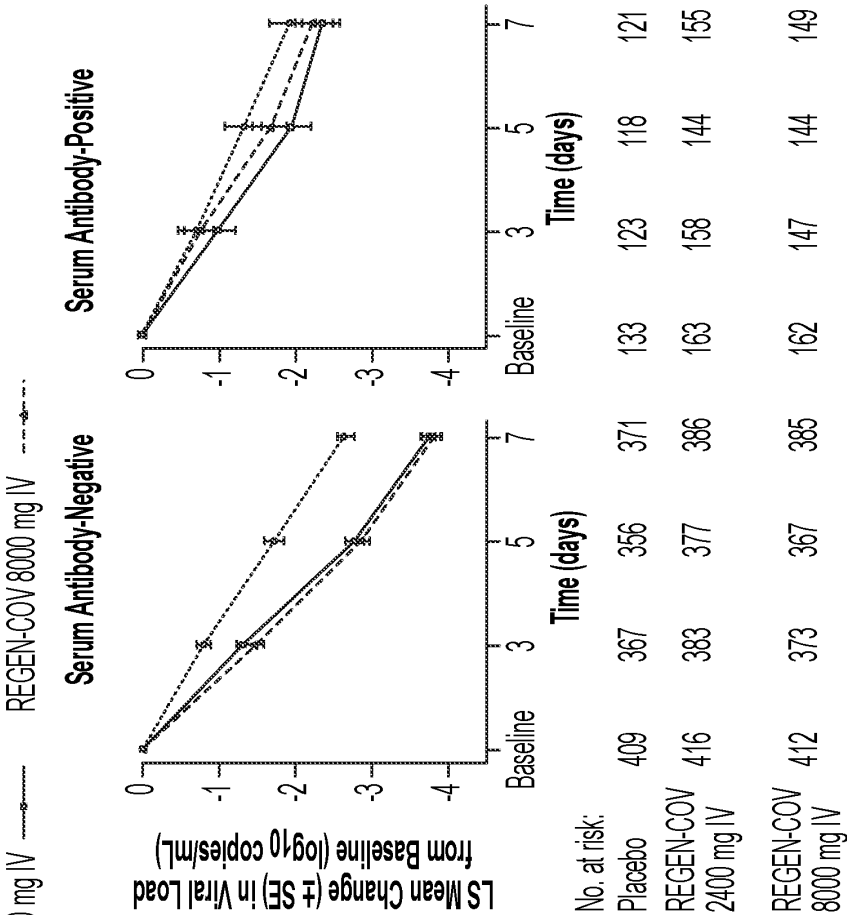
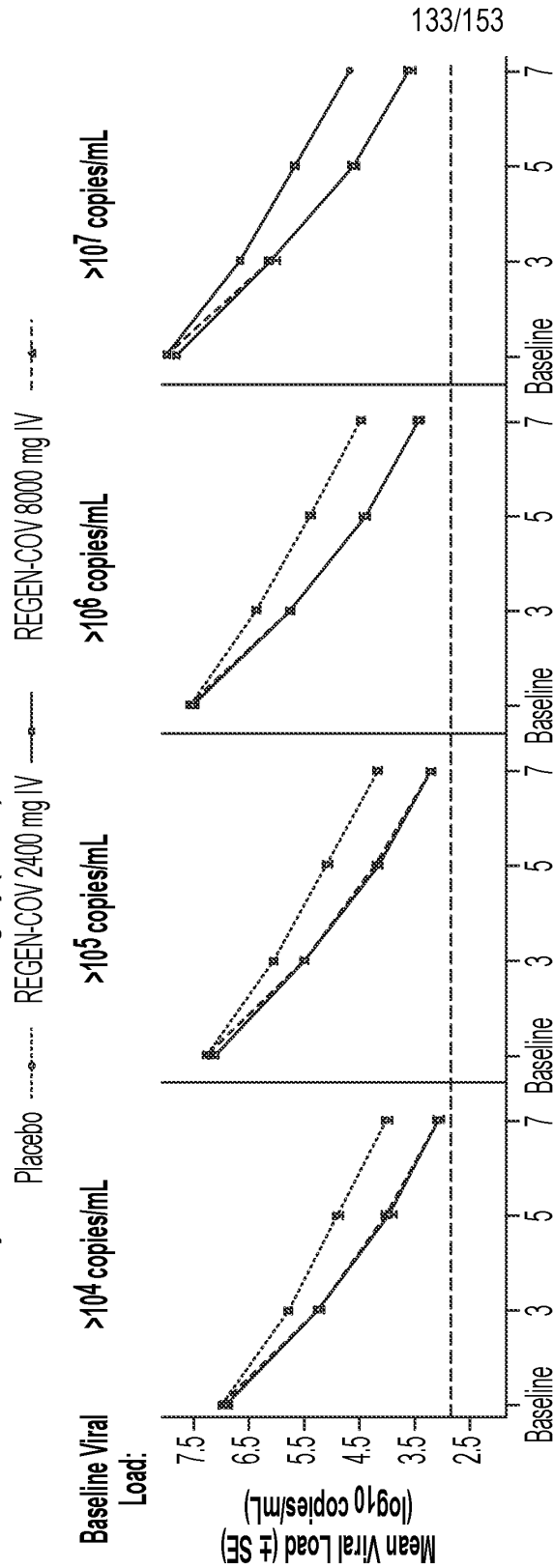


FIG. 88B

C. Viral Load Over Time by Baseline Viral Load Category (mFAS)*



No. at risk:	Time (days)																
Placebo	538	488	469	484	483	434	419	434	405	364	352	365	303	269	260	273	
REGEN-COV 2400 mg IV	567	525	505	527	511	471	454	473	425	390	381	394	305	275	275	285	
REGEN-COV 8000 mg IV	566	511	504	524	506	455	448	469	428	386	382	396	313	285	282	290	

* The lower limit of detection (dashed line) is 714 copies per milliliter (2.85 log₁₀ copies per milliliter). mFAS, modified full analysis set; IV, intravenous, SE, standard error.

FIG. 88C

134/153

Phase 3 Primary Analysis Hierarchical Testing Order

The analysis of the primary endpoint (proportion of patients with ≥ 1 COVID-19-related hospitalization or all-cause death through day 29) and key secondary endpoint (time to symptom resolution) will be conducted at the overall $\alpha=0.05$. The endpoints will be tested hierarchically in the following order, adjusting for interim analysis:

Hierarchy Number	Description
1	Proportion of patients with ≥ 1 COVID-19-related hospitalization or all-cause death through day 29 in the mFAS for REGEN-COV 2400 mg group versus placebo
2	Proportion of patients with ≥ 1 COVID-19-related hospitalization or all-cause death through day 29 in the mFAS for REGEN-COV 1200 mg group versus placebo
3	Proportion of patients with ≥ 1 COVID-19-related hospitalization or all-cause death through day 29 in the mFAS patients with baseline viral load $>10^6$ copies/mL for REGEN-COV 2400 mg group versus placebo
4	Proportion of patients with ≥ 1 COVID-19-related hospitalization or all-cause death through day 29 in the mFAS patients who are seronegative at baseline for REGEN-COV 2400 mg group versus placebo
5	Proportion of patients with ≥ 1 COVID-19-related hospitalization or all-cause death through day 29 in the mFAS patients with baseline viral load $>10^6$ copies/mL for REGEN-COV 1200 mg group versus placebo
6	Proportion of patients with ≥ 1 COVID-19-related hospitalization or all-cause death through day 29 in the mFAS patients who are seronegative at baseline for REGEN-COV 1200 mg group versus placebo
7	Proportion of patients with ≥ 1 COVID-19-related hospitalization or all-cause death from day 4 through day 29 in the mFAS for REGEN-COV 2400 mg group versus placebo
8	Proportion of patients with ≥ 1 COVID-19-related hospitalization or all-cause death from day 4 through day 29 in the mFAS for REGEN-COV 1200 mg group versus placebo
9	Time to COVID-19 symptoms resolution in the mFAS for REGEN-COV 2400 mg group versus placebo
10	Time to COVID-19 symptoms resolution in the mFAS for REGEN-COV 1200 mg group versus placebo

mFAS, modified full analysis set.

FIG. 89

Protocol-Defined Risk Factors for Severe Covid-19 (mFAS)

Protocol-defined risk factor — no. (%) [¶]	Placebo (n=1341)	REGEN-COV 1200 mg (n=736)	REGEN-COV 2400 mg (n=1355)	REGEN-COV 8000 mg (n=625)	Total (n=4057)
Age ≥50 years	678 (50.6)	357 (48.5)	715 (52.8)	351 (56.2)	2101 (51.8)
Obesity (BMI ≥30 kg/m ²)	772 (57.6)	410 (55.7)	787 (58.1)	384 (61.4)	2353 (58.0)
Cardiovascular disease, including hypertension	473 (35.3)	282 (38.3)	520 (38.4)	196 (31.4)	1471 (36.3)
Chronic lung disease, including asthma	219 (16.3)	139 (18.9)	216 (15.9)	92 (14.7)	666 (16.4)
Type 1 or 2 diabetes mellitus	210 (15.7)	94 (12.8)	202 (14.9)	97 (15.5)	603 (14.9)
Chronic kidney disease, including those on dialysis	9 (0.7)	8 (1.1)	19 (1.4)	9 (1.4)	45 (1.1)
Chronic liver disease	8 (0.6)	3 (0.4)	14 (1.0)	11 (1.8)	36 (0.9)
Immunocompromised*	34 (2.5)	24 (3.3)	46 (3.4)	16 (2.6)	120 (3.0)

BMI, body mass index; mFAS, modified full analysis set.

* The most common immunosuppressive conditions were rheumatoid arthritis, HIV/AIDS, and systemic lupus erythematosus; the most common immunosuppressive medications were hydroxychloroquine, antimetabolites, and TNF inhibitors.

FIG. 90

Demographic and Baseline Medical Characteristics (mFAS) - 8000 mg REGEN-COV

Characteristic*	REGEN-COV 8000 mg (n=625)	Placebo (8000 mg) (concurrent) (n=593)
Demographics		
Median age (IQR) — year	51.0 (40.0-59.0)	50.0 (39.0-58.0)
Baseline age category — no. (%)		
Age ≥50 years	351 (56.2)	322 (54.3)
Age ≥65 years	97 (15.5)	56 (9.4)
Male sex — no. (%)	324 (51.8)	281 (47.4)
Hispanic or Latino ethnic group — no. (%)†	177 (28.3)	176 (29.7)
Race — no. (%)†		
White	534 (85.4)	525 (88.5)
Black or African American	33 (5.3)	28 (4.7)
Asian	26 (4.2)	20 (3.4)
American Indian or Alaska Native	3 (0.5)	3 (0.5)
Unknown	15 (2.4)	6 (1.0)
Not reported	14 (2.2)	11 (1.9)
Median weight (IQR) — kg	89.85 (76.20-106.60)	88.50 (75.00-104.00)

FIG. 91

Body-mass index†	31.90±7.229	31.35±6.846
Obesity — no. (%)§	384 (61.4)	345 (58.2)
At least one risk factor for severe Covid-19 — no. (%)¶	625 (100)	593 (100)
Medical/Clinical Characteristics		
Positive baseline qualitative RT-PCR — no. (%)	625 (100)	589 (99.3)
Baseline viral load in nasopharyngeal swab (raw values)		
No. of patients	625	589
Mean viral load — (10 ⁶) copies/ml	170.03 ± 555.7	194.01 ± 628.9
Median viral load (range) — (10 ⁶) copies/ml	10.10 (0-6090)	11.20 (0-6780)
Baseline viral load in nasopharyngeal swab (log ₁₀ scale)		
No. of patients	625	589
Mean viral load — log ₁₀ copies/ml	6.64 ± 1.671	6.70 ± 1.664
Median viral load (range) — log ₁₀ copies/ml	7.00 (2.6-9.8)	7.05 (2.6-9.8)
Baseline serum C-reactive protein level		
No. of patients	544	519
Mean level — mg/l	14.206 ± 28.0260	12.794 ± 23.9368
Median level (range) — mg/l	5.065 (0.18-228.07)	5.020 (0.10-242.73)

FIG. 91 (Cont.)

Baseline serum antibody status — no. (%)		
Negative	412 (65.9)	411 (69.3)
Positive	162 (25.9)	133 (22.4)
Other	51 (8.2)	49 (8.3)
Median time from symptom onset to randomization (IQR) — days	3.0 (2–5)	3.0 (2–5)

* Plus-minus values are means ±SD. Percentages may not total 100 because of rounding. IQR denotes interquartile range, RT-PCR reverse-transcriptase polymerase chain reaction, and SD standard deviation.

† Race and ethnic group were reported by the patients.

‡ The body-mass index is the weight in kilograms divided by the square of the height in meters.

§ Obesity is defined as a body-mass index of greater than or equal to 30.

¶ Risk factors for hospitalization include an age of more than 50 years, obesity, cardiovascular disease (including hypertension), chronic lung disease (including asthma), chronic metabolic disease (including diabetes), chronic kidney disease (including receipt of dialysis), chronic liver disease, and immunocompromised (immunosuppression or receipt of immunosuppressants).

FIG. 91 (Cont.)

Proportion of Patients in the Placebo Arm with ≥1 Covid-19-related Hospitalization or All-cause Death by Baseline Viral Load Category

End Point	Placebo (concurrent with REGEN-COV 2400 mg)	Placebo (concurrent with REGEN-COV 1200 mg)
Proportion of patients with ≥1 Covid-19-related hospitalization or all-cause death		
Baseline viral load category: high viral load (>10 ⁶ copies/mL)		
No. of patients	876	471
Patients with event within 29 days — no. (%)	55 (6.3)	20 (4.2)
Baseline viral load category: low viral load (≤10 ⁶ copies/mL)		
No. of patients	457	273
Patients with event within 29 days — no. (%)	6 (1.3)	4 (1.5)

FIG. 92

Viral Load in the Placebo Arm by With and Without Hospitalization or Death and by Baseline Serum Antibody Status

Baseline Serum Antibody Status:	Coid-19-related Hospitalization or Death	Baseline SARS-CoV-2 Viral Load (log10 copies/ml) (Mean ± SD)	Day 7 SARS-CoV-2 Viral Load (log10 copies/ml) (Mean ± SD)
All			
n=1272	No	6.62 ± 1.77	3.60 ± 2.13
n=61	Yes	7.54 ± 1.18	5.36 ± 1.35
Negative			
n=877	No	7.16 ± 1.49	4.03 ± 2.01
n=48	Yes	7.61 ± 1.09	5.41 ± 1.36
Positive			
n=283	No	5.04 ± 1.62	2.46 ± 2.04
n=12	Yes	7.06 ± 1.35	5.08 ± 1.39

SD, standard deviation.

FIG. 93

Proportion of Patients with ≥ 1 Covid-19-related Hospitalization or All-cause Death

End Point	REGEN-COV 2400 mg (n=1355)	Placebo (2400 mg) (concurrent) (n=1341)	REGEN-COV 1200 mg (n=736)	Placebo (1200 mg) (concurrent) (n=748)
Proportion of patients with ≥ 1 Covid-19-related hospitalization or all-cause death				
Patients with event within 29 days — no. (%)	18 (1.3)	62 (4.6)	7 (1.0)	24 (3.2)
Relative risk reduction vs placebo — percentage points	71.3		70.4	
95% CI†	51.7, 82.9		31.6, 87.1	
Proportion of patients with hospitalization				
Patients with event within 29 days — no. (%)	17 (1.3)	59 (4.4)	6 (0.8)	23 (3.1)
Relative risk reduction vs placebo — percentage points	71.5		73.5	
95% CI†	51.3, 83.3		35.3, 89.1	
Proportion of patients with all-cause death				
Patients with event within 29 days — no. (%)	1 (<0.1)	3 (0.2)	1 (0.1)	1 (0.1)
Relative risk reduction vs placebo — percentage points	67.0		-1.6	
95% CI†	-216.7, 96.6		-1522, 93.6	

CI, confidence interval.

† 95% CI used the Farrington-Manning method.

FIG. 94

Proportion of Patients with ≥ 1 Covid-19-related MAV or All-cause Death

End Point*	REGEN-COV 2400 mg (n=1355)	Placebo (2400 mg) (concurrent) (n=1341)	REGEN-COV 1200 mg (n=736)	Placebo (1200 mg) (concurrent) (n=748)
Proportion of patients with ≥ 1 Covid-19-related MAV or all-cause death				
Patients with event within 29 days — no. (%)	43 (3.2)	109 (8.1)	20 (2.7%)	51 (6.8)
Relative risk reduction vs placebo — percentage points	61.0		60.1	
95% CI†	44.9, 72.3		33.8, 76.0	
Proportion of patients with hospitalization				
Patients with event within 29 days — no. (%)	17 (1.3)	59 (4.4)	6 (0.8)	23 (3.1)
Relative risk reduction vs placebo — percentage points	71.5		73.5	
95% CI†	51.3, 83.3		35.3, 89.1	
Proportion of patients with emergency room visit				
Patients with event within 29 days — no. (%)	9 (0.7)	16 (1.2)	2 (0.3)	10 (1.3)
Relative risk reduction vs placebo — percentage points	44.3		79.7	
95% CI†	-25.5, 75.3		7.5, 95.5	
Proportion of patients with urgent care visit				
Patients with event within 29 days — no. (%)	3 (0.2)	7 (0.5)	1 (0.1)	5 (0.7)
Relative risk reduction vs placebo — percentage points	57.6		79.7	
95% CI†	-63.7, 89.0		-73.6, 97.6	

FIG. 95

Proportion of patients with physician office/telemedicine visit				
Patients with event within 29 days — no. (%)	13 (1.0)	24 (1.8)	10 (1.4)	12 (1.6)
Relative risk reduction vs placebo — percentage points	46.4		15.3	
95% CI†	-4.8, 72.6		-94.8, 63.2	
Proportion of patients with all-cause death				
Patients with event within 29 days — no. (%)	1 (<0.1)	3 (0.2)	1 (0.1)	1 (0.1)
Relative risk reduction vs placebo — percentage points	67.0		-1.6	
95% CI†	-216.7, 96.6		-1522, 93.6	

CI, confidence interval; MAV, medically-attended visit.

* A patient with multiple types of events was only counted to the worst level event, following this decreasing order: all-cause death, hospitalization, ER, urgent care, physician office visit/telemedicine.

† 95% CI used the Farrington-Manning method.

FIG. 95 (Cont.)

Hospitalization Outcomes: Length of Stay, ICU, and Mechanical Ventilation

End Point	REGEN-COV 2400 mg (n=1355)	Placebo (2400 mg) (concurrent) (n=1341)	REGEN-COV 1200 mg (n=736)	Placebo (1200 mg) (concurrent) (n=748)
Days of hospitalization due to COVID-19 per patient				
No. of patients	18	62	7	24
Mean (SD)	8.6 ± 7.07	10.0 ± 7.16	7.0 ± 8.04	8.4 ± 6.74
Median (IQR)	6.0 (3.0-11.0)	7.0 (5.0-13.0)	4.0 (3.0-6.0)	5.5 (4.0-10.5)
Proportion of patients admitted to an ICU				
Patients with event within 29 days — no. (%)	6 (0.4)	18 (1.3)	3 (0.4)	7 (0.9)
Relative risk reduction vs placebo — percentage points	67.0		56.4	
95% CI*	17.2, 86.9		-67.8, 88.7	
Proportion of patients requiring mechanical ventilation				
Patients with event within 29 days — no. (%)	1 (<0.1)	6 (0.4)	1 (0.1)	2 (0.3)
Relative risk reduction vs placebo — percentage points	83.5		49.2	
95% CI*	-36.8, 98.0		-459.2, 95.4	

CI, confidence interval; ICU, intensive care unit, IQR, interquartile range, SD, standard deviation.

* 95% CI used the Farrington-Manning method.

FIG. 96

Proportion of Patients with ≥1 Covid-19-related Hospitalization, Emergency Room Visits, or All-cause Death

End Point	REGEN-COV 2400 mg (n=1355)	Placebo (2400 mg) (concurrent) (n=1341)	REGEN-COV 1200 mg (n=736)	Placebo (1200 mg) (concurrent) (n=748)
Proportion of patients with events				
Patients with event within 29 days — no. (%)	27 (2.0)	78 (5.8)	9 (1.2)	34 (4.5)
Relative risk reduction vs placebo — percentage points	65.7		73.1	
95% CI*	47.3, 77.7		44.3, 87.0	

CI, confidence interval.

* 95% CI used the Farrington-Manning method.

FIG. 97

Proportion of Patients with ≥1 Covid-19-related Hospitalization or All-cause Death - 8000 mg REGEN-COV

End Point	REGEN-COV 8000 mg (n=625)	Placebo (8000 mg) (concurrent) (n=593)
Proportion of patients with ≥1 COVID-19-related hospitalization or all-cause death		
Patients with event within 29 days — no. (%)	13 (2.1)	38 (6.4)
Relative risk reduction vs placebo — percentage points	67.5	
95% CI†	39.7, 82.5	
Proportion of patients with hospitalization		
Patients with event within 29 days — no. (%)	13 (2.1)	36 (6.1)
Relative risk reduction vs placebo — percentage points	65.7	
95% CI†	36.0, 81.6	
Proportion of patients with all-cause death		
Patients with event within 29 days — no. (%)	0	2 (0.3)
Relative risk reduction vs placebo — percentage points	100.0	
95% CI†	n/a	

CI, confidence interval.

† 95% CI used the Farrington-Manning method.

FIG. 98

Proportion of Patients with ≥1 Covid-19-related MAV or All-cause Death - 8000 mg REGEN-COV

End Point*	REGEN-COV 8000 mg (n=625)	Placebo (8000 mg) (concurrent) (n=593)
Proportion of patients with ≥1 Covid-19-related MAV or all-cause death		
Patients with event within 29 days — no. (%)	26 (4.2)	58 (9.8)
Relative risk reduction vs placebo — percentage points	57.5	
95% CI†	33.4, 72.8	
Proportion of patients with hospitalization		
Patients with event within 29 days — no. (%)	13 (2.1)	36 (6.1)
Relative risk reduction vs placebo — percentage points	65.7	
95% CI†	36.0, 81.6	
Proportion of patients with emergency room visit		
Patients with event within 29 days — no. (%)	3 (0.5)	6 (1.0)
Relative risk reduction vs placebo — percentage points	52.6	
95% CI†	-88.8, 88.1	
Proportion of patients with urgent care visit		
Patients with event within 29 days — no. (%)	2 (0.3)	2 (0.3)
Relative risk reduction vs placebo — percentage points	5.1	
95% CI†	-571.4, 86.6	

FIG. 99

Proportion of patients with physician office/telemedicine visit		
Patients with event within 29 days — no. (%)	8 (1.3)	12 (2.0)
Relative risk reduction vs. placebo — percentage points	36.7	
95% CI†	-53.6, 74.0	
Proportion of patients with all-cause death		
Patients with event within 29 days — no. (%)	0	2 (0.3)
Relative risk reduction vs. placebo — percentage points	100.0	
95% CI†	n/a	

CI, confidence interval; MAV, medically-attended visit.

* A patient with multiple types of events was only counted to the worst level event, following this decreasing order: all-cause death, hospitalization, ER, urgent care, physician office visit/telemedicine.

† 95% CI used the Farrington-Manning method.

FIG. 99 (Cont.)

Treatment-Emergent Adverse Events Leading to Death

System Organ Class Preferred Term	Placebo (n=1476)	REGEN-COV 1200 mg IV (n=827)	REGEN-COV 2400 mg IV (n=1512)	REGEN-COV 8000 mg IV (n=689)	Total (n=4504)
<i>no. of patients (percent)</i>					
Number of patients with at least one treatment-emergent adverse event leading to death					
TEAE leading to death	5 (0.3)	1 (0.1)	1 (<0.1)	0	7 (0.2)
Treatment-emergent adverse event leading to death by system organ class and preferred term					
Respiratory, thoracic and mediastinal disorders					
Dyspnoea	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)
Acute respiratory distress syndrome	1 (<0.1)	0	0	0	1 (<0.1)
Hypoxia	0	1 (0.1)	0	0	1 (<0.1)
Respiratory failure	1 (<0.1)	0	0	0	1 (<0.1)
Infections and infestations					
COVID-19	1 (<0.1)	0	0	0	1 (<0.1)
COVID-19 pneumonia	1 (<0.1)	0	0	0	1 (<0.1)
Pneumonia	1 (<0.1)	0	0	0	1 (<0.1)
Neoplasms benign, malignant and unspecified (including cysts and polyps)					
Tumor obstruction	1 (<0.1)	0	0	0	1 (<0.1)

FIG. 100

Treatment-Emergent Serious Adverse Events and Adverse Events of Special Interest

System Organ Class Preferred Term*	Placebo (n=1843)	REGEN-COV 1200 mg IV (n=827)	REGEN-COV 2400 mg IV (n=1849)	REGEN-COV 8000 mg IV (n=1012)	Total (n=5531)
<i>no. of patients (percent)†</i>					
Serious treatment-emergent adverse events by system organ class and preferred term					
Infections and infestations					
COVID-19	18 (1.0%)	1 (0.1%)	5 (0.3%)	5 (0.5%)	29 (0.5%)
COVID-19 pneumonia	14 (0.8%)	2 (0.2%)	4 (0.2%)	5 (0.5%)	25 (0.5%)
Pneumonia	17 (0.9%)	2 (0.2%)	3 (0.2%)	1 (<0.1%)	23 (0.4%)
Respiratory, thoracic and mediastinal disorders					
Dyspnoea	7 (0.4%)	0	1 (<0.1%)	1 (<0.1%)	9 (0.2%)
Hypoxia	6 (0.3%)	1 (0.1%)	1 (<0.1%)	1 (<0.1%)	9 (0.2%)
Acute respiratory failure	3 (0.2%)	0	2 (0.1%)	1 (<0.1%)	6 (0.1%)
Respiratory distress	2 (0.1%)	0	0	0	2 (<0.1%)
Metabolism and nutrition disorders					
Dehydration	2 (0.1%)	0	0	0	2 (<0.1%)
Hyponatraemia	2 (0.1%)	0	0	0	2 (<0.1%)

FIG. 101

Adverse events of special interest by preferred term					
COVID-19	11 (0.6%)	2 (0.2%)	4 (0.2%)	2 (0.2%)	19 (0.3%)
Dyspnoea	9 (0.5%)	3 (0.4%)	3 (0.2%)	1 (<0.1%)	16 (0.3%)
Cough	2 (0.1%)	3 (0.4%)	2 (0.1%)	1 (<0.1%)	8 (0.1%)
Pneumonia	6 (0.3%)	2 (0.2%)	0	0	8 (0.1%)
COVID-19 pneumonia	4 (0.2%)	2 (0.2%)	0	1 (<0.1%)	7 (0.1%)
Headache	2 (0.1%)	2 (0.2%)	1 (<0.1%)	1 (<0.1%)	6 (0.1%)
Dizziness	1 (<0.1%)	2 (0.2%)	1 (<0.1%)	0	4 (<0.1%)
Nausea	0	2 (0.2%)	0	1 (<0.1%)	3 (<0.1%)
Pulmonary congestion	1 (<0.1%)	0	0	2 (0.2%)	3 (<0.1%)
Nasal congestion	2 (0.1%)	0	0	0	2 (<0.1%)

* Term included if ≥2 patients in any of the individual dose groups.

†A patient who reported 2 or more adverse events with different preferred terms within the same system organ class is counted only once in that system organ class. A patient who reported 2 or more adverse events with the same preferred term is counted only once for that term. A patient who reported 2 or more adverse events with the same preferred term is counted only once for that term. If a patient had more than one occurrence in the same event category, only the most related was counted.

FIG. 101 (Cont.)

Adverse Events of Special Interest - Patients Requiring Medical Attention at a Healthcare Facility					
	Placebo (n=1476)	REGEN-COV 1200 mg IV (n=827)	REGEN-COV 2400 mg IV (n=1512)	REGEN-COV 8000 mg IV (n=689)	Total (n=4504)
<i>no. of patients (percent)</i>					
Patients requiring medical attention at a healthcare facility					
Related to Covid-19	44 (3.0)	15 (1.8)	19 (1.3)	10 (1.5)	88 (2.0)
Not related to Covid-19	5 (0.3)	0	7 (0.5)	0	12 (0.3)

FIG. 102

Mean (SD) [N] Pharmacokinetic Parameters of REGN10933 and REGN10987 in Serum

Pharmacokinetic Parameter	REGN10933 (casirivimab)*			REGN10987 (imdevimab)*		
	600 mg	1200 mg	4000 mg	600 mg	1200 mg	4000 mg
C _{eo1} (mg/L)†	185 (74.5) [158]	321 (106) [553]	1049 (317) [388]	192 (78.9) [171]	321 (112) [580]	1049 (308) [400]
C ₂₈ (mg/L)‡	46.4 (22.5) [127]	73.2 (27.2) [609]	238 (86.1) [482]	38.3 (19.6) [127]	60.0 (22.9) [610]	192 (70.2) [469]
Estimated t _{1/2} in days (90% CI)§	28.8 (16.5, 41.1)			25.5 (17.4, 33.7)		

C, concentration; eo1, end of infusion; IV, intravenous; SD, standard deviation; t_{1/2}, half-life.

* Mean (SD) [N], where N is number of observations

† Concentration at the end of infusion (1 hour)

‡ Observed concentration 28 days after dosing, i.e., on day 29

§ Based on 2-compartment population pharmacokinetic models developed for casirivimab and imdevimab from approximately 3700 patients across different REGN-COV clinical trials, including this study (2067). Half-life estimates represent values for the 1200 mg IV, 2400 mg IV, and 8000 mg IV doses combined.

FIG. 103