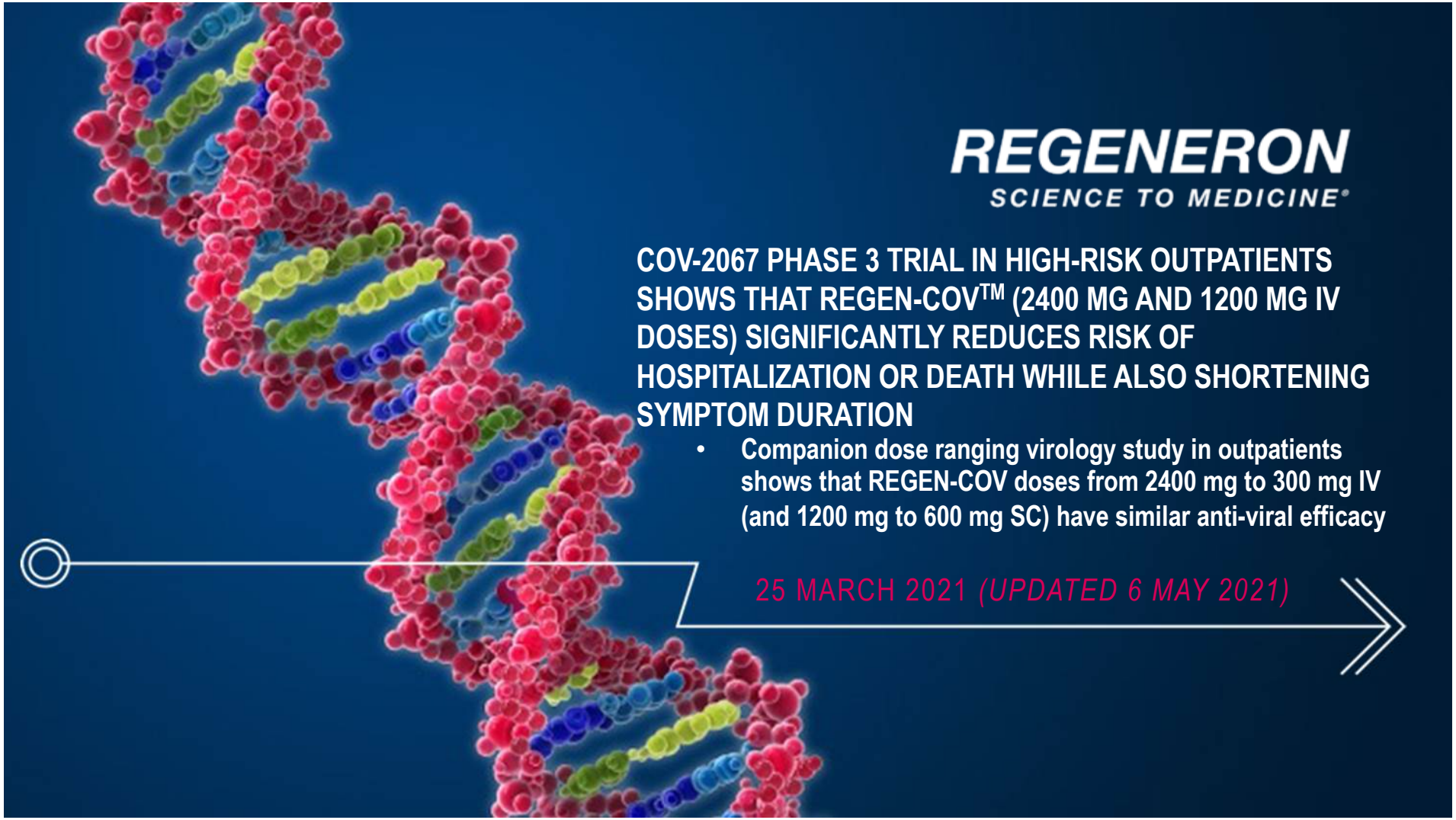

REGENERON
SCIENCE TO MEDICINE®
COV-2067 PHASE 3 TRIAL IN HIGH-RISK OUTPATIENTS SHOWS THAT REGEN-COV™ (2400 MG AND 1200 MG IV DOSES) SIGNIFICANTLY REDUCES RISK OF HOSPITALIZATION OR DEATH WHILE ALSO SHORTENING SYMPTOM DURATION
• Companion dose ranging virology study in outpatients shows that REGEN-COV doses from 2400 mg to 300 mg IV (and 1200 mg to 600 mg SC) have similar anti-viral efficacy
25 MARCH 2021 (UPDATED 6 MAY 2021)

- REGEN-COV has not been FDA-approved, but has been authorized for emergency use by the FDA under an Emergency Use Authorization (EUA). Its safety and efficacy have not been fully evaluated by any regulatory authority.
- REGEN-COV is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the EUA under section 564(b)(1) of the Food Drug and Cosmetic Act, unless the authorization is terminated or revoked sooner.

1-2M INDIVIDUALS ARE STILL INFECTED EACH MONTH IN THE U.S. ALONE, RESULTING IN TENS OF THOUSANDS OF DEATHS: MEDICAL IMPERATIVE TO TREAT EACH HIGH-RISK PATIENT

- We now have compelling data confirming the profound anti-viral activity of the REGEN-COV Antibody Cocktail, as well as its profound ability to protect high-risk patients from progressing to Hospitalization or Death (as well as its ability to decrease symptom duration by ~4 days, on average)
- The REGEN-COV Antibody Cocktail retains its potency against the most dangerous and concerning emerging variants
- We now have the supply chain to treat about 0.5M patients a month – a large proportion if not all high-risk patients (currently only ~10,000 patients are treated each month, resulting in unnecessary and devastating loss of life)

It's time to raise awareness and renew confidence in the "monoclonal antibody" approach, and widely inform about the value of making sure we treat every single high-risk patient in the U.S., as keeping patients from progressing to severe COVID-19 should save many lives

- ❖ Tens of thousands of lives at stake every month
- ❖ Such widespread treatment should also slow the spread of concerning variants, that may ultimately otherwise undermine natural- and vaccine-immunity

REGEN-COV CLINICAL PROGRAM: EXPLORING THE COVID-19 DISEASE SPECTRUM

Pre-Infection

Post-Infection

PCR(-) / High Risk Exposure

PCR(+) for SARS-COV-2

"Household Contact" Prophylaxis Trial (2069)

"Outpatient" Trial (2067)

"Hospitalized Patient" Trial(s) (2066)
4 distinct trial populations, studied independently

Endpoint: Reduction in Hospitalization or Death

Oxygen Requirement

None (Cohort 1A)	Low Flow (Cohort 1)	High Flow (Cohort 2)	Mech. Ventilated (Cohort 3)

Endpoint: Prevention of symptomatic infection, in those at high risk due to living in household with "infected index patient"

"Outpatient" Trial (20145)

Evaluating antiviral efficacy of lower doses

Endpoint: Reduction in Death or Requiring Mechanical Ventilation (separately assessed in each cohort)

UK NHS RECOVERY Phase 3 Trial
Endpoint: Mortality

PHASE 3 STUDY SCHEMATIC FROM 2067 ADAPTIVE OUTPATIENT TRIAL

Based on Phase 1/2 results showing 8000 mg and 2400 mg doses similarly reduce medically-attended visits for COVID-19 (FDA HCP EUA Fact Sheet), study amended to instead compare 2400 mg vs 1200 mg doses

Patient Population:

- Adult, *non-hospitalized* COVID-19 patients
- Symptom onset ≤7 days from randomization
- SARS-CoV-2 confirmed by molecular testing ≤72 hours from randomization
- Not on any putative COVID-19 therapies

Original Phase 3 portion comparing 8000 mg and 2400 mg versus placebo

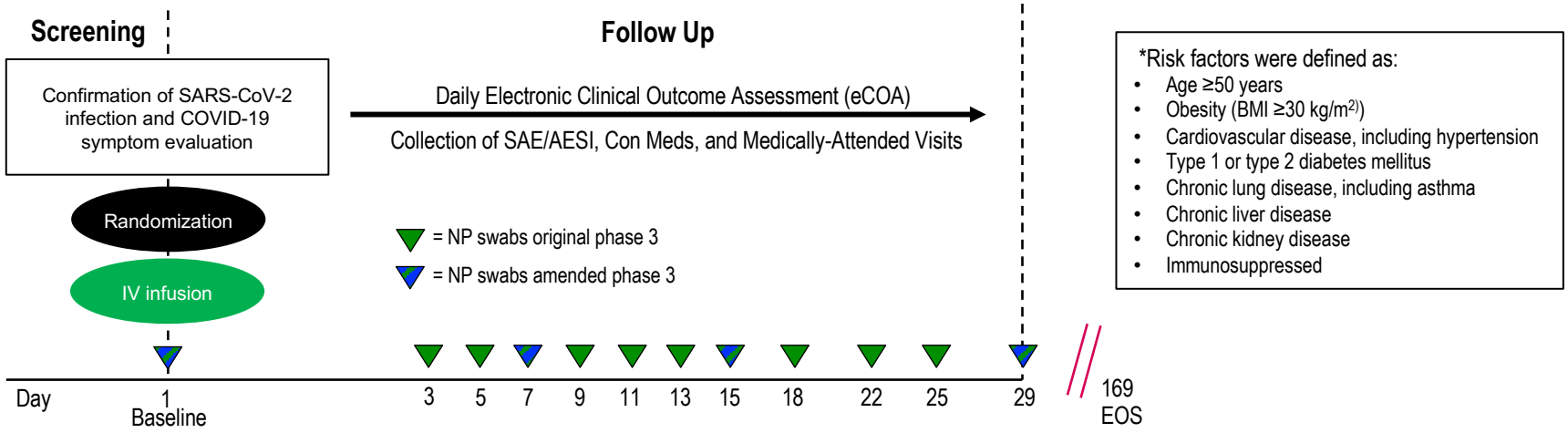
R 1:1:1
- REGEN-COV 8000 mg IV
- REGEN-COV 2400 mg IV
- Placebo IV

Stratified by no risk factors vs at least 1 risk factor for severe COVID-19

Amended Phase 3 portion comparing 2400 mg and 1200 mg versus placebo

R 1:1:1
- REGEN-COV 2400 mg IV
- REGEN-COV 1200 mg IV
- Placebo IV

All patients required to have at least 1 risk factor for severe COVID-19*

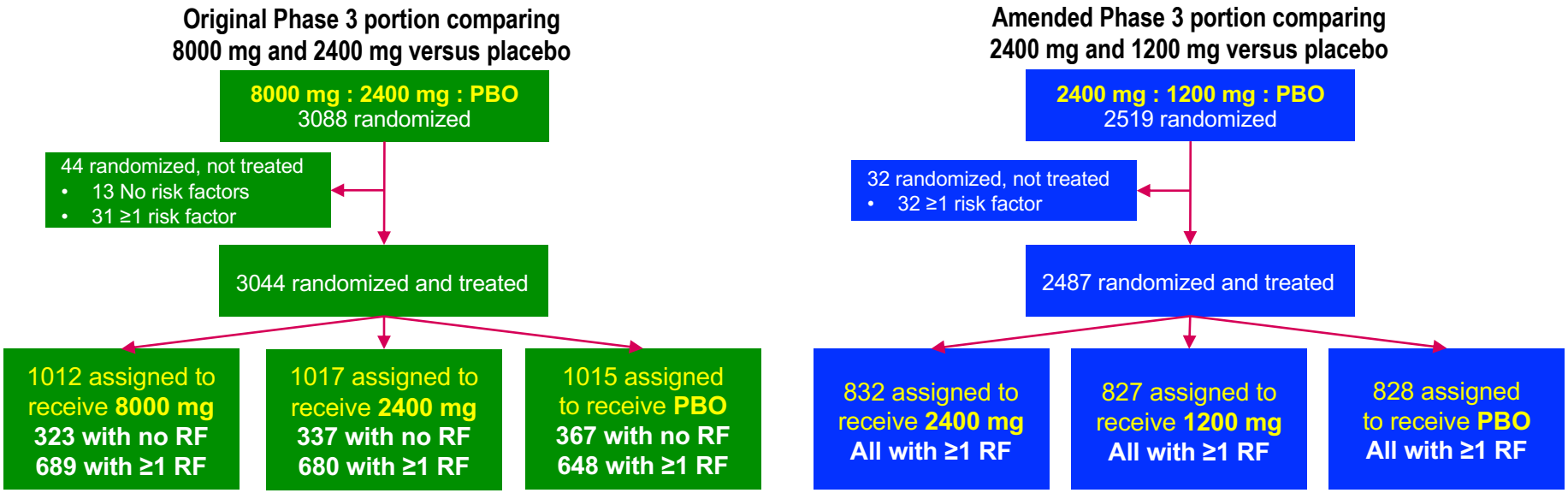


*Risk factors were defined as:

- Age ≥50 years
- Obesity (BMI ≥30 kg/m$^{2)}$)
- Cardiovascular disease, including hypertension
- Type 1 or type 2 diabetes mellitus
- Chronic lung disease, including asthma
- Chronic liver disease
- Chronic kidney disease
- Immunosuppressed

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

PHASE 3: ENROLLMENT AS OF 17JAN2021 FOR PATIENTS TO BE INCLUDED IN FINAL ANALYSIS (ALLOWING A MINIMUM OF 28 DAYS FOLLOW UP)



Based on final analysis of Phase 1/2 portion of 2067 (FDA HCP EUA Fact Sheet), which showed that the 8000 mg and 2400 mg doses were indistinguishable on antiviral and clinical endpoints (and that clinical events were largely occurring in high-risk patients), the Phase 3 protocol was amended to compare 2400 mg and 1200 mg versus placebo in high-risk patients only.

- Data comparing 8000 mg to placebo was converted to descriptive analysis
- Formal hierarchical analysis first evaluated 2400 mg dose versus concurrent placebo (in patients with ≥1 risk factor from original and amended portions, n = ~2700) and then evaluated 1200 mg dose versus concurrent placebo (in patients with ≥1 risk factor, n = ~1500)

PROTOCOL-DEFINED RISK FACTOR WERE WELL-BALANCED

mFAS COHORT: PATIENTS ≥18 YEARS WHO ARE SARS-COV-2 PCR+ AT BASELINE AND HAVE ≥1 RISK FACTOR FOR SEVERE COVID-19

Protocol-Defined Risk Factors	Overall Placebo N=1341	1200 mg N=736	2400 mg N=1355	8000 mg N=625
Age ≥50 years, (%)	50.6%	48.5%	52.8%	56.2%
Obesity (BMI ≥30 kg/m^2), (%)	57.6%	55.7%	58.1%	61.4%
Cardiovascular Disease, including hypertension, (%)	35.3%	38.3%	38.4%	31.4%
Chronic Lung disease, including asthma, (%)	16.3%	18.9%	15.9%	14.7%
Type 1 or 2 Diabetes Mellitus, (%)	15.7%	12.8%	14.9%	15.5%
Chronic Kidney Disease, (%)	0.7%	1.1%	1.4%	1.4%
Chronic Liver Disease, (%)	0.6%	0.4%	1.0%	1.8%
Immunosuppressed, (%)	2.5%	3.3%	3.4%	2.6%

mFAS (modified full analysis set): 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

DEMOGRAPHICS AND BASELINE CHARACTERISTICS WERE WELL-BALANCED

mFAS COHORT: PATIENTS ≥18 YEARS WHO ARE SARS-COV-2 PCR+ AT BASELINE AND HAVE ≥1 RISK FACTOR FOR SEVERE COVID-19

PHASE 3 PATIENTS HAVE HIGHER BASELINE VIRAL LOAD AND HIGHER BASELINE SERONEGATIVITY THAN PATIENTS IN PHASE 1/2 (HIGHLIGHTED TEXT)

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
Median Age (IQR; Q1:Q3)	49 (38:58)	50 (39:60)	50 (37:58)	48.5 (37:57.5)	48 (35:57)	51 (40:59)
Age ≥50 years (%)	48.0%	52.8%	50.6%	48.5%	47.6%	56.2%
Age ≥65 years (%)	11.0%	15.8%	10.7%	12.6%	11.8%	15.5%
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/m)	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 copies/mL, (%)	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

2067 PHASE 3: REGEN-COV REDUCES COVID-19-RELATED HOSPITALIZATION OR ALL-CAUSE DEATH, AND SHORTENS TIME TO SYMPTOMS RESOLUTION; 1200 MG AND 2400 MG PERFORM SIMILARLY

20145 DOSE RANGING VIROLOGIC EFFICACY STUDY: SINGLE DOSES OF 300 MG IV OR 600 MG SC SHOW SIMILAR VIROLOGIC EFFICACY TO HIGHER DOSES

2067 outpatient clinical outcomes trial (n=4567)

- **REGEN-COV significantly reduces COVID-19-related hospitalization or all-cause death in high-risk COVID-19 patients**
  - Similar treatment effect with the two dose levels: **2400 mg vs PBO, 71.3% reduction** (1.3% vs 4.6%; p<0.0001); **1200 mg vs PBO, 70.4% reduction** (1.0% vs 3.2%; p=0.0024)
- **REGEN-COV results in faster symptoms resolution:** 2400 mg vs PBO, median 10 vs 14 days; p<0.0001; 1200 mg vs PBO, median 10 vs 14 days; p<0.0001

20145 outpatient dose ranging virology efficacy trial (n=803): 2400, 1200, 600 & 300 mg IV; 1200 & 600 mg SC;

- **Dose ranging study in low-risk patients (asymptomatic, or symptomatic with no risk factors): All 6 REGEN-COV dose levels tested showed significant and comparable virologic reduction through day 7 in patients who were SARS-CoV-2 PCR+ and seronegative at baseline**

Safety (2067, n=5531; 20145, n=803): largest safety database to date for anti-SARS-CoV-2 monoclonal antibodies

- **REGEN-COV generally safe and well-tolerated; no serious safety signal, no safety dose response observed; few (<0.1%) IRRs / hypersensitivity reactions**
  - In 2067 outcomes study, SAEs (including fatal events) more frequent in the PBO group compared to REGEN-COV dose groups (4.0% PBO vs 1.4% combined REGEN-COV)
  - In 20145 dose-ranging study, no fatalities, 2 SAEs, both assessed as not related to COVID-19 or study drug

In a Phase 3 trial in 4567 high-risk patients, REGEN-COV significantly reduced COVID-19 hospitalization or all-cause death, and shortened time to symptom resolution by 4 days, confirming clinical benefit seen in Phase 1/2

In the dose-ranging virologic efficacy study in 803 low-risk patients, REGEN-COV significantly and substantially reduced viral load across all dose levels tested, down to as low as single doses of 300 mg IV or 600 mg SC

REGEN-COV has an acceptable safety profile at all dose levels; no safety signal observed in outpatient studies

PHASE 3 CONFIRMS CLINICAL EFFICACY OF REGEN-COV; TREATMENT SIGNIFICANTLY REDUCES COVID-19-RELATED HOSPITALIZATION OR ALL-CAUSE DEATH AND DURATION OF SYMPTOMS

SIMILAR TREATMENT EFFECT IN THE TWO DOSE LEVELS

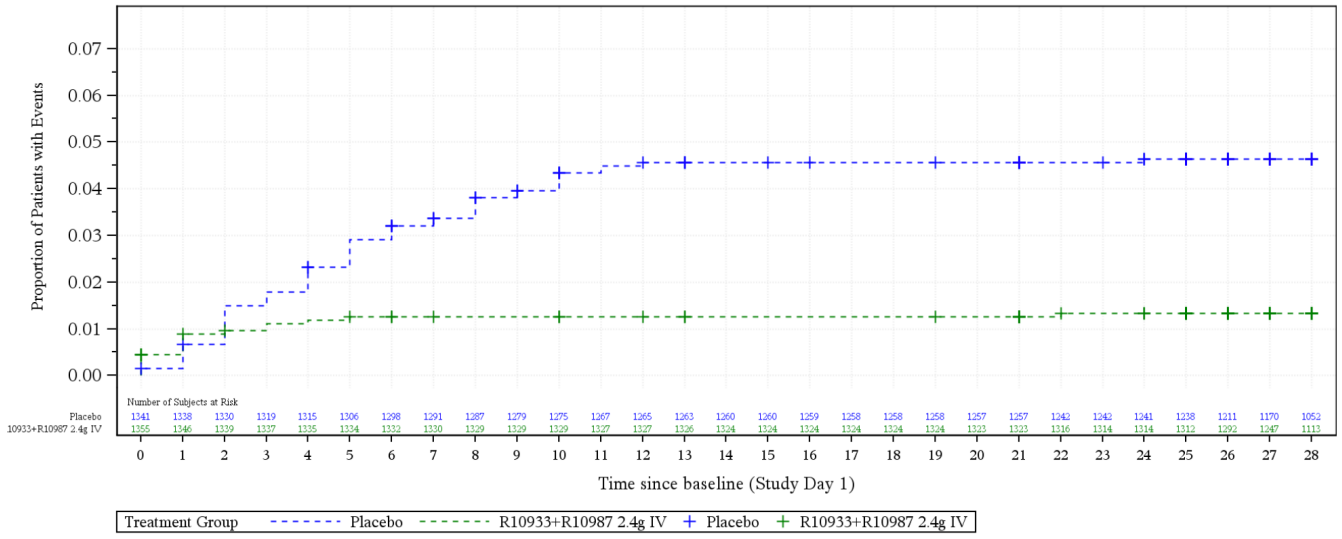
Hypothesis Testing Hierarchy*	Comparison	Treatment effect
1. Proportion of patients with ≥1 COVID-19-related hospitalization or all-cause death through day 29	2400 mg vs PBO	**71.3% reduction**; 18/1355 (1.3%) vs 62/1341 (4.6%) 95% CI (51.7%, 82.9%); p<0.0001
2. Proportion of patients with ≥1 COVID-19-related 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
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; 5/735** (0.7%) vs 18/748 (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)

*all analyses in 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

RISK FOR COVID-19 HOSPITALIZATION OR ALL-CAUSE DEATH REDUCED BY 71%† WITH 2400 MG REGEN-COV COMPARED TO PLACEBO

Overall mFAS Population (2400 mg vs placebo)

Figure 14.2.1.1.1M.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)



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

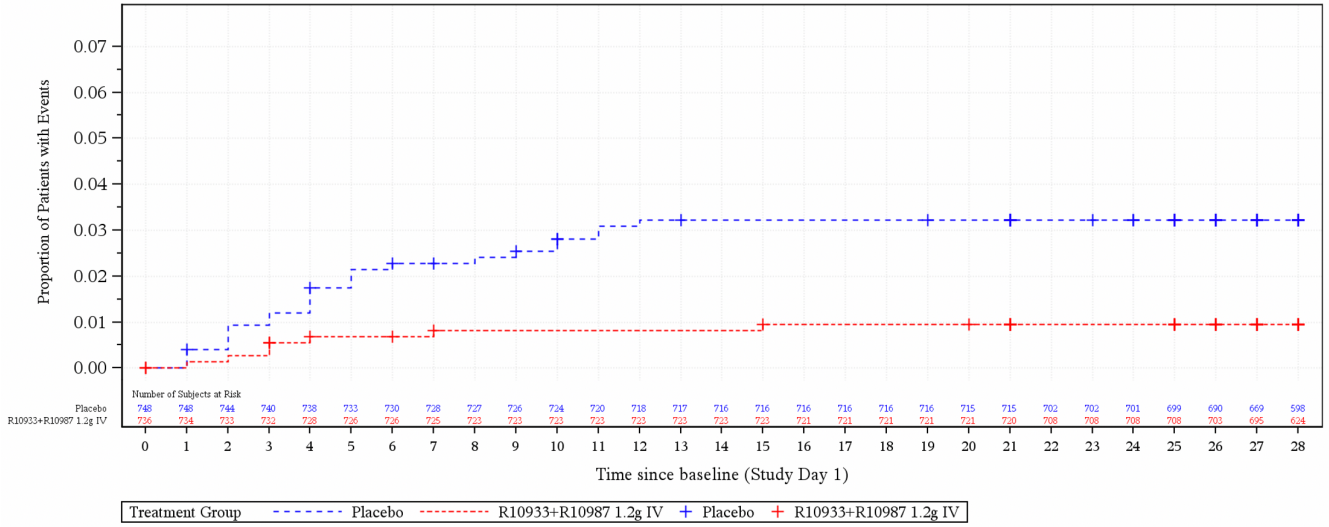
†HR vs. placebo (95% CI)
2400 mg: 0.29 (0.17, 0.49); p < 0.0001

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

RISK FOR COVID-19 HOSPITALIZATION OR ALL-CAUSE DEATH REDUCED BY 71%† WITH 1200 MG REGEN-COV COMPARED TO PLACEBO

Overall mFAS Population (1200 mg vs placebo)

Figure 14.2.1.1.1MP6a Kaplan Meier Curve for Time to COVID-19-related Hospitalization or All-cause Death through Day 29 for R10933+R10987 1.2 g IV
Phase 3 Cohort 1 with >= 1 Risk Factor for Severe COVID-19 post PA6
Modified Full Analysis Set (mFAS)



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

†HR vs. placebo (95% CI)

1200 mg: 0.29 (0.13, 0.68); p = 0.0014

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

SUMMARY OF POOLED DATA (WITHOUT REGARD TO CONCURRENT CONTROL)
POOLED DEATHS ACROSS ENTIRE SAFETY POPULATION
POOLED HOSPITALIZATIONS THROUGH D29

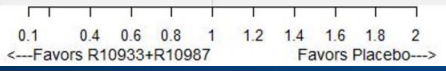
Endpoint	Group	Placebo	1.2g	2.4g	Rel Risk Reduction
Deaths	Safety Population	5 / 1843 (0.3%)	1 / 827 (0.1%)	1 / 1849 (<0.1%)	1.2g: 56% 2.4g: 80%
Hospitalizations	mFAS to Day 29 Combined	59 / 1341 (4.4%)	6 / 736 (0.8%)	17 / 1355 (1.3%)	74% *

*Compared to 73% for 1.2g & 71% for 2.4g versus their concurrently randomized placebo

BOTH DOSES OF REGEN-COV ASSOCIATED WITH SIMILAR RISK REDUCTION IN COVID-19-RELATED HOSPITALIZATION OR ALL-CAUSE DEATH ACROSS SUBGROUPS

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

	R10933+R10987 Events/N (%)	Placebo Events/N (%)	Relative Risk (95% CI)	Rel. Risk Reduction (95% CI)	P
mFAS					
1200 mg vs Placebo	7/736 (1.0)	24/748 (3.2)		70% (32%, 87%)	0.0024
2400 mg vs Placebo	18/1355 (1.3)	62/1341 (4.6)		71% (52%, 83%)	<0.0001
Baseline Viral Load >10^6 copies/mL					
1200 mg vs Placebo	6/482 (1.2)	20/471 (4.2)		71% (28%, 88%)	0.0045
2400 mg vs Placebo	13/924 (1.4)	55/876 (6.3)		78% (59%, 88%)	<0.0001
Baseline Viral Load <=10^6 copies/mL					
1200 mg vs Placebo	1/252 (0.4)	4/273 (1.5)		73% (-141%, 97%)	0.3746
2400 mg vs Placebo	5/429 (1.2)	6/457 (1.3)		11% (-189%, 73%)	1
Baseline Seronegative					
1200 mg vs Placebo	3/500 (0.6)	18/519 (3.5)		83% (42%, 95%)	0.0014
2400 mg vs Placebo	12/940 (1.3)	49/930 (5.3)		76% (55%, 87%)	<0.0001
Baseline Seropositive					
1200 mg vs Placebo	1/177 (0.6)	6/164 (3.7)		85% (NA, 98%)	0.0588
2400 mg vs Placebo	4/323 (1.2)	12/297 (4.0)		69% (6%, 90%)	0.04



Overall (8000 mg vs PBO): Hosp/Death: 67.5% reduction, (95% CI; 39.7%, 82.5%), 2.1% v 6.4%, nominal p=0.0002
Seronegative (8000 mg vs PBO): Hosp/Death: 83.9% reduction, (95% CI; 59.0%, 93.7%), 1.2% v 7.5%, nominal p=<0.0001
>10^6 copies/mL (8000 mg vs PBO): Hosp/Death: 81.1% reduction, (95% CI; 57.9%, 91.5%), 1.6% v 8.6%, nominal p=<0.0001

VIRUS DRIVES SERIOUS DISEASE: PATIENTS ON PLACEBO WITH EVENTS (HOSPITALIZATIONS OR DEATH) HAD HIGHER BASELINE VIRUS LEVELS & CLEARED VIRUS MORE SLOWLY

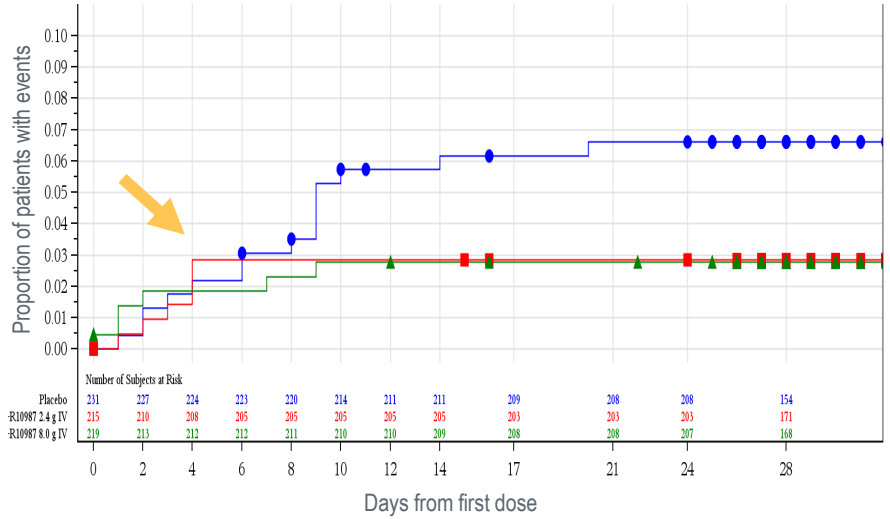
Similar to seronegative patients, seropositive patients who had events had high baseline viral levels as well as high Day 7 viral levels, arguing that they had an "ineffective antibody response"

Baseline SAR-CoV-2 Serology	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
All (n=61)	Yes	7.54 ± 1.18	5.36 ± 1.35
Seronegative (n=877)	No	7.16 ± 1.49	4.03 ± 2.01
Seronegative (n=48)	Yes	7.61 ± 1.09	5.41 ± 1.36
Seropositive (N=283)	No	5.04 ± 1.62	2.46 ± 2.04
Seropositive (N=12)	Yes	7.06 ± 1.35	5.08 ± 1.39

2067 PHASE 3 RESULTS CONSISTENT WITH PRIOR PHASE 2 TRIALS

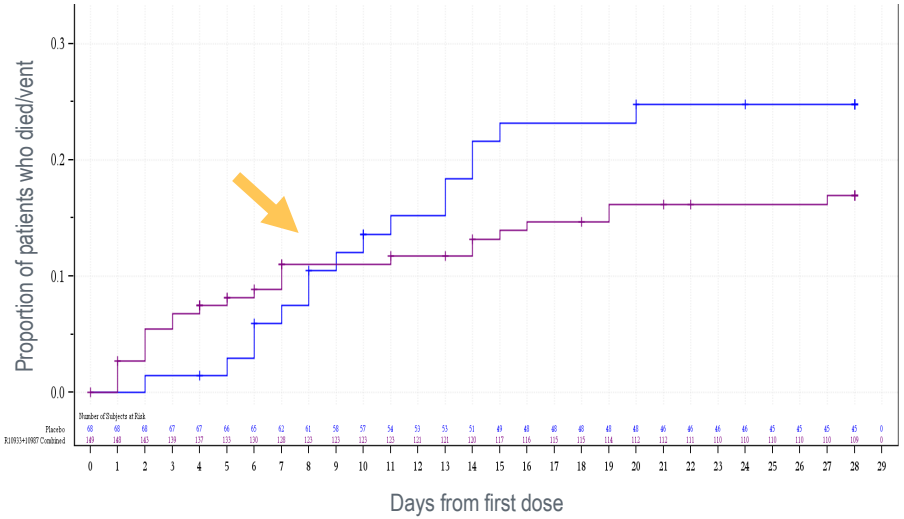
2067 OUTPATIENTS Ph3: ~60-80% REDUCED MEDICALLY-ATTENDED VISITS (E.G., ER VISITS & HOSPITALIZATIONS)
2066 HOSPITALIZED Ph3: ~32% REDUCED RISK OF DEATH OR MECHANICAL VENTILATION

2067 Outpatient Phase 2 Trial
(Overall population, N=665)



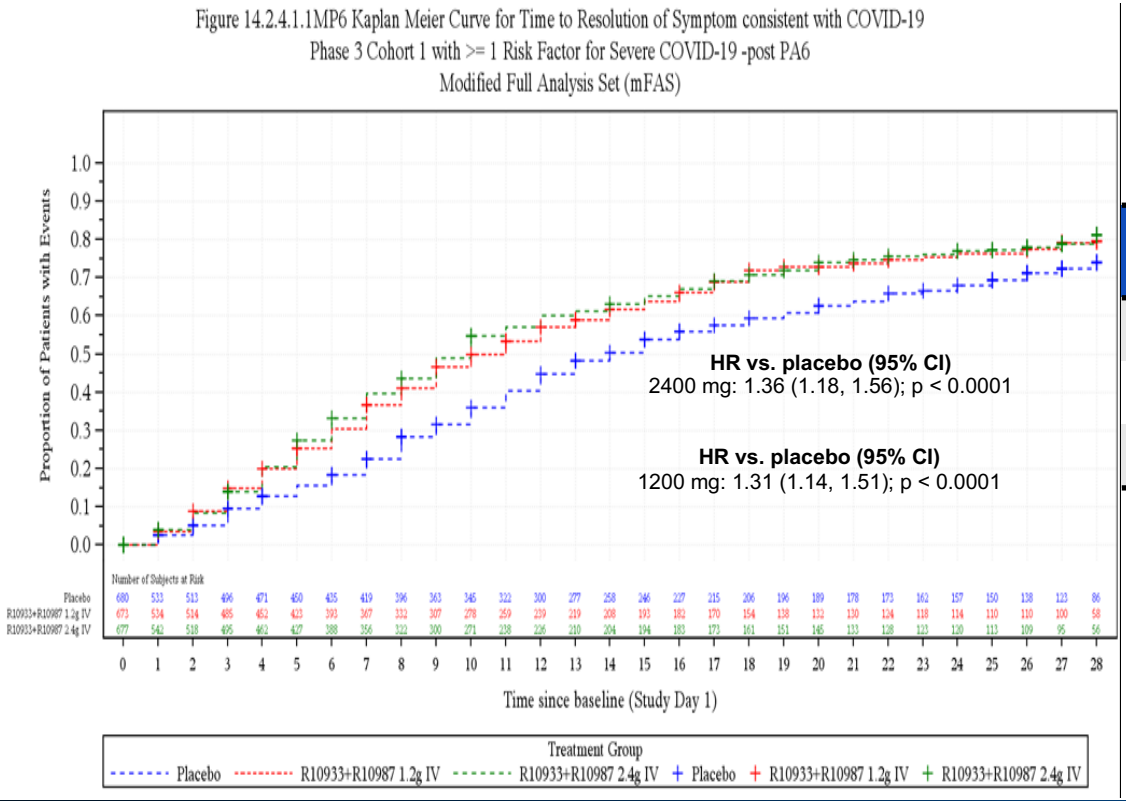
HR vs. placebo (95% CI)
Low dose: 0.4 (0.2, 1.1); p=0.04
High dose: 0.4 (0.2, 1.1); p=0.04

2066 Hospitalized Patient Phase 2 Trial
(Seronegative at baseline population, N=217)



REGEN-COV associated with a 31.5% reduced risk of death and mechanical ventilation (80% CI: -1.03% to -52.65%, p=0.095)

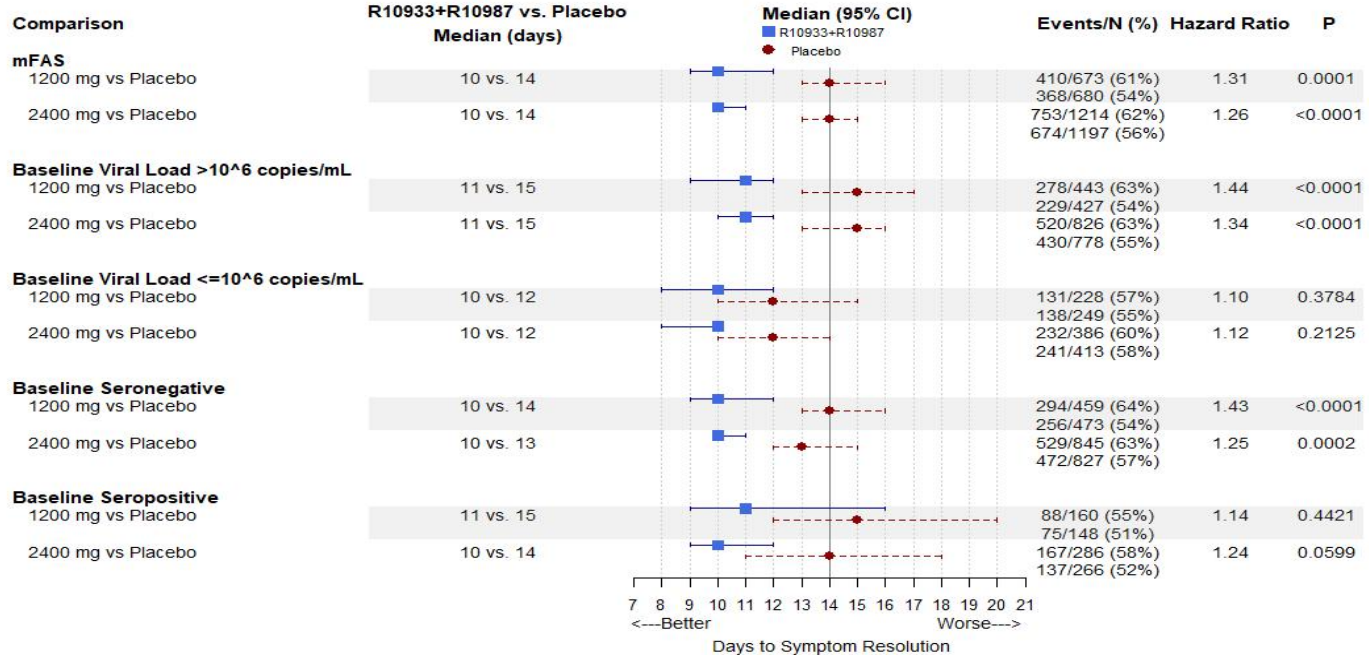
BOTH DOSES OF REGEN-COV ASSOCIATED WITH 4 DAYS SHORTER MEDIAN TIME TO COVID-19 SYMPTOMS RESOLUTION COMPARED TO CONTROL GROUP



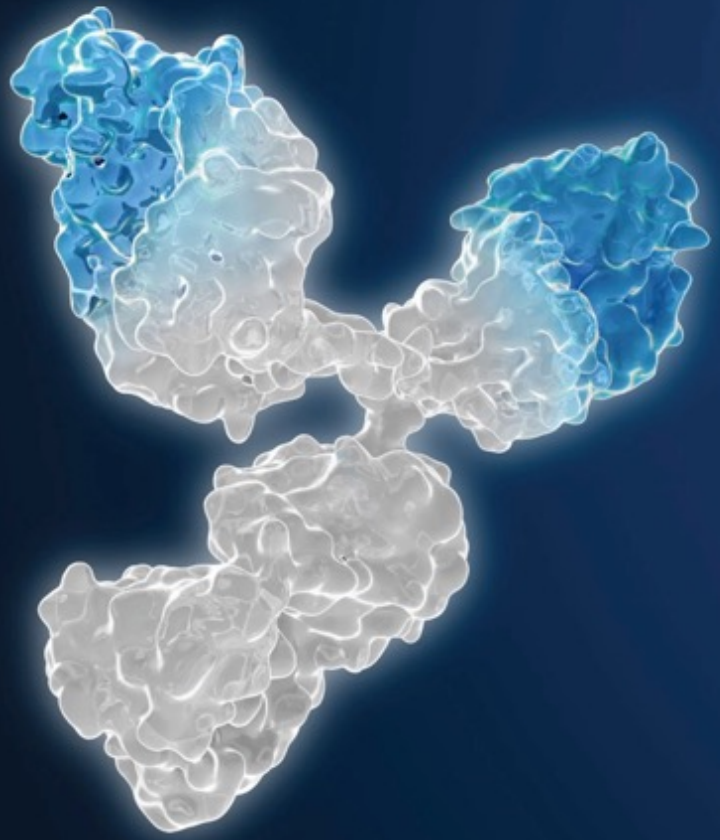
Arm	Median Days	95% (LCL , UCL)
Placebo	14	(13,16)
2400 mg	10	(9,10)
1200 mg	10	(9,12)

BOTH DOSES OF REGEN-COV ASSOCIATED WITH SIMILAR IMPROVEMENTS IN SYMPTOM RESOLUTION ACROSS SUBGROUPS

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



Higher viral loads associated with longer symptom duration



VIROLOGIC EFFICACY IN 2067 OUTPATIENT TRIAL

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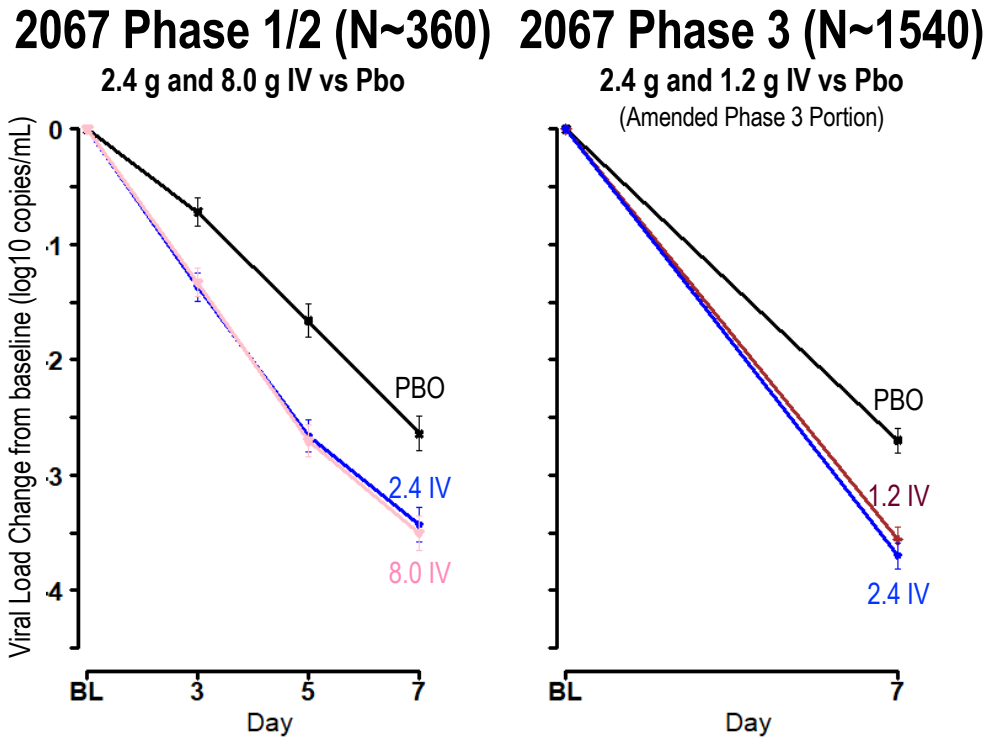
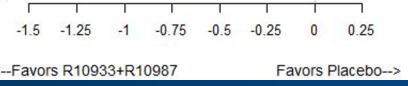
CHANGE FROM BASELINE IN VIRAL LOAD SHOW COMPARABLE RESULTS BETWEEN PHASE 1/2 AND PHASE 3 2067 TRIALS

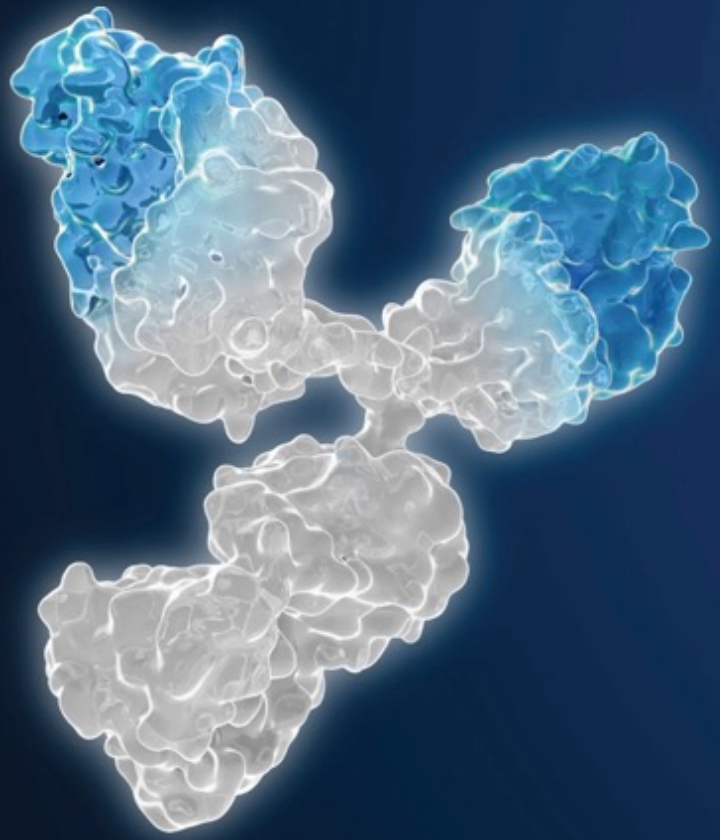


BOTH DOSES OF REGEN-COV ASSOCIATED WITH SIMILAR REDUCTION IN VIRAL LOAD AT DAY 7 ACROSS SUBGROUPS

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 >10^6 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





20145 Trial

- Companion dose ranging virology study in outpatients shows that REGEN-COV doses from 2400 mg to 300 mg IV (and 1200 mg to 600 mg SC) have similar anti-viral efficacy

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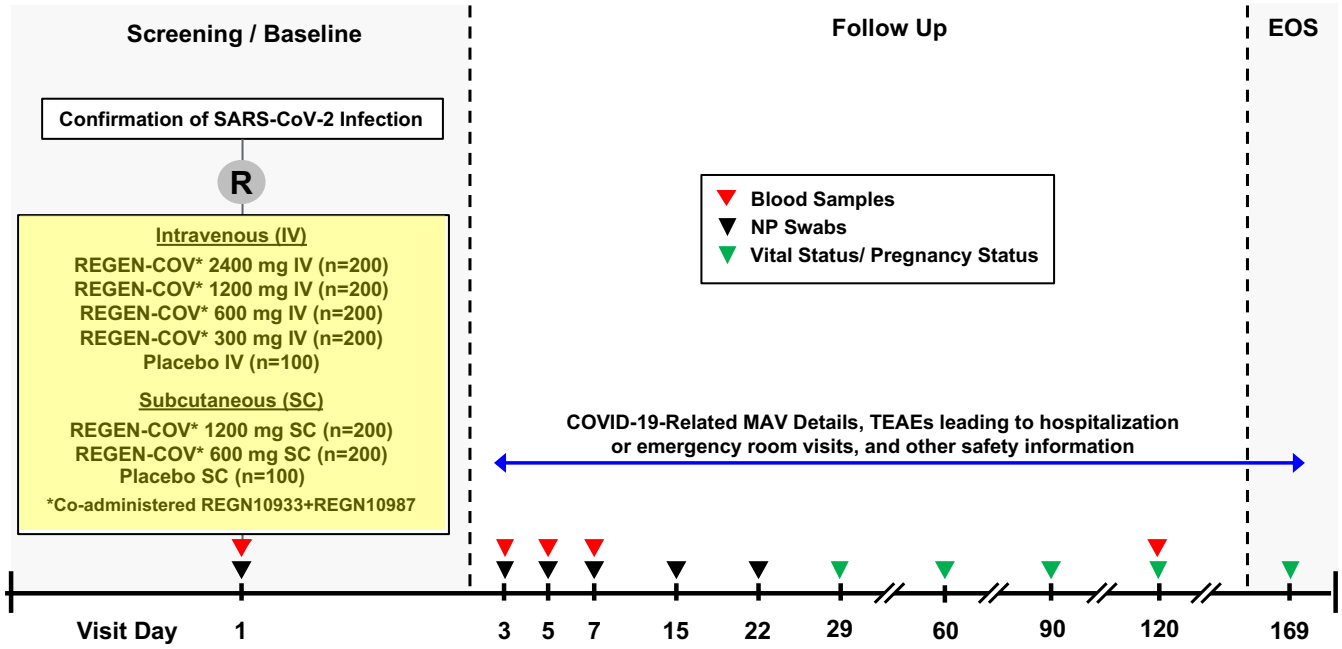
20145 TRIAL TO ASSESS THE VIROLOGIC EFFICACY OF REGEN-COV ACROSS DIFFERENT DOSE REGIMENS IN OUTPATIENTS WITH SARS-COV-2 INFECTION

Primary Objective:
To assess the virologic efficacy of REGEN-COV across different intravenous (IV) and subcutaneous (SC) doses compared to placebo

- Randomized, double-blind, placebo-controlled
- Parallel group study
- Not a non-inferiority trial
- No stratification



DEMOGRAPHICS AND BASELINE CHARACTERISTICS FOR SERONEGATIVE IV PATIENTS (SERONEGATIVE mFAS) - GROUPS ARE WELL BALANCED

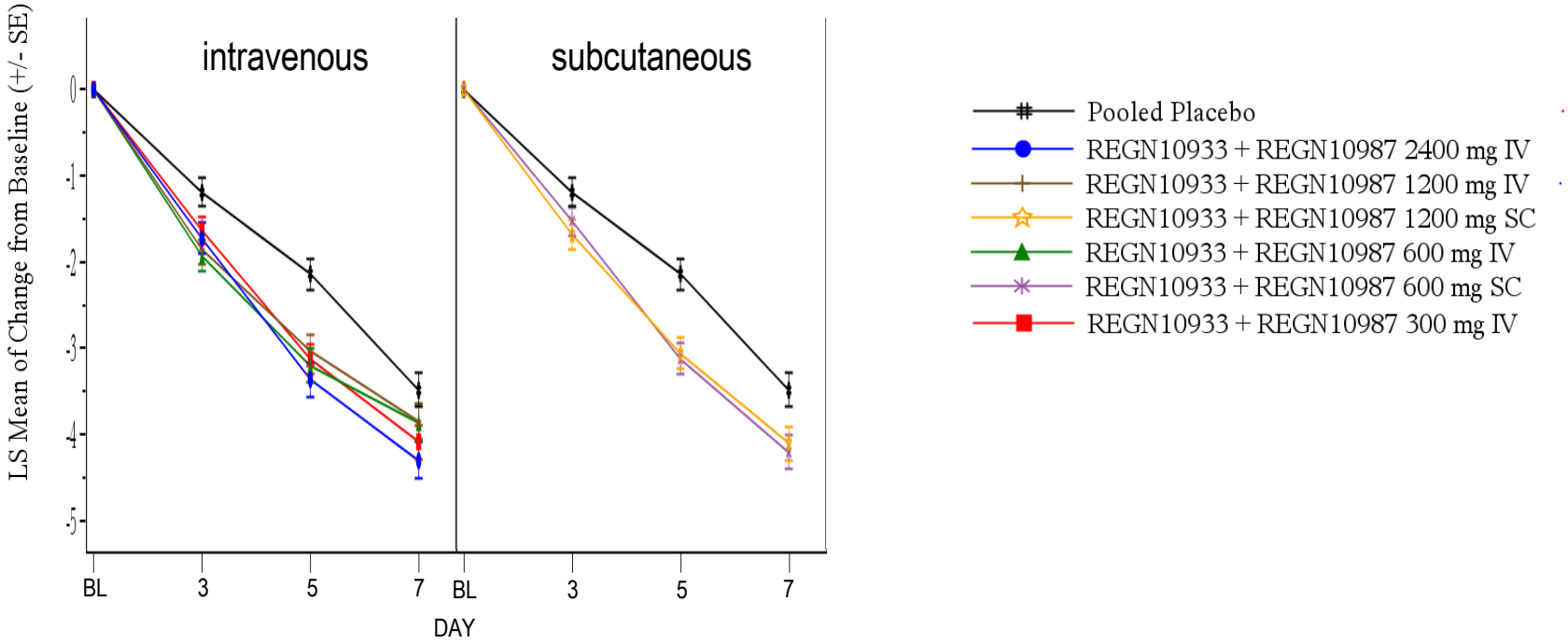
	Pooled Placebo (N=77)	REGEN-COV 300 mg IV (N=80)	REGEN-COV 600 mg IV (N=68)	REGEN-COV 1200 mg IV (N=72)	REGEN-COV 2400 mg IV (N=62)	Total (N=359)
Age (years)						
Mean (SD)	35.1 (9.97)	33.8 (8.90)	33.9 (9.16)	34.1 (10.51)	36.3 (9.16)	34.6 (9.55)
Sex, n (%)						
Male	31 (40.3%)	33 (41.3%)	39 (57.4%)	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)

DEMOGRAPHICS AND BASELINE CHARACTERISTICS FOR SERONEGATIVE SC PATIENTS (SERONEGATIVE mFAS) – GROUPS ARE WELL BALANCED

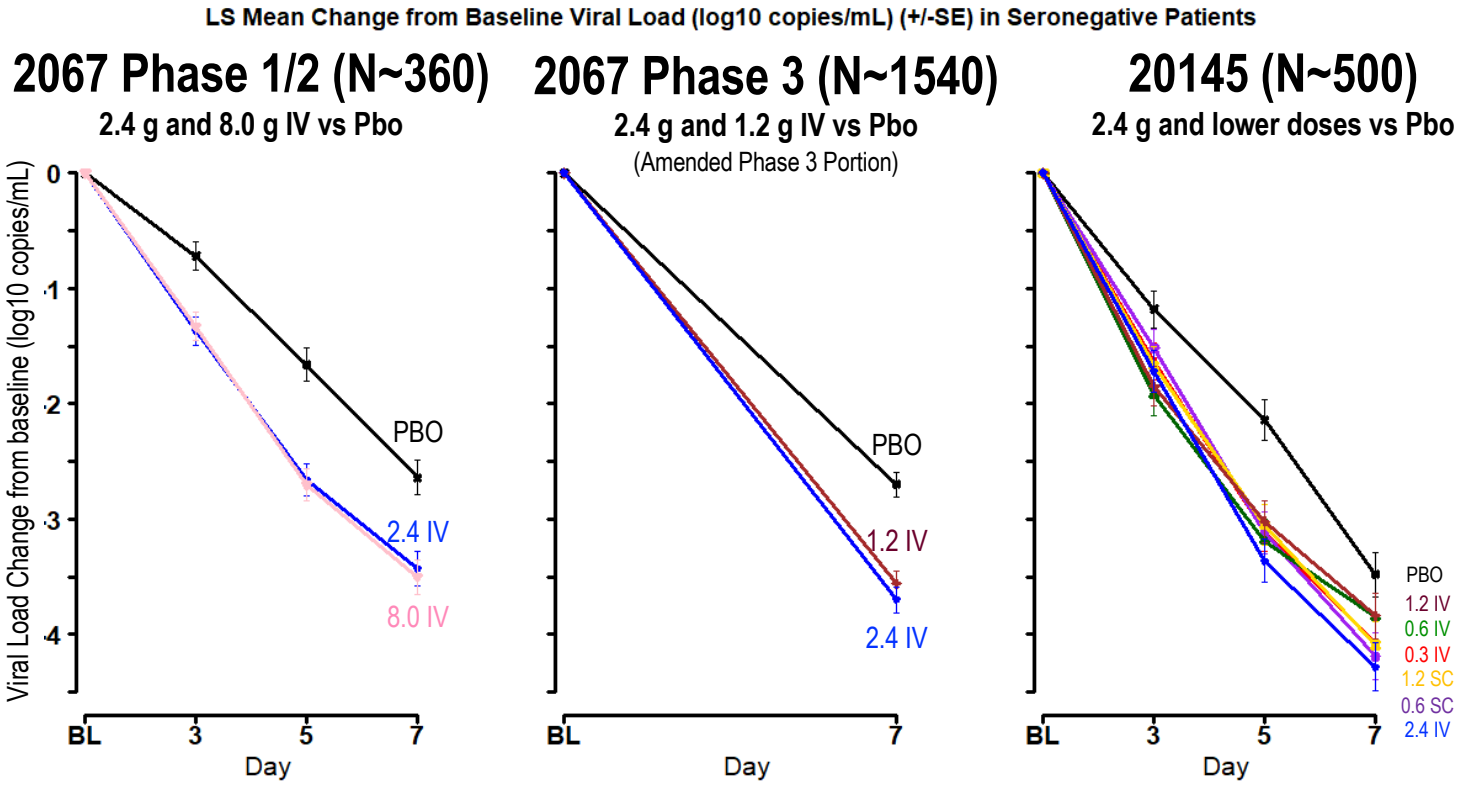
	Pooled Placebo (N=77)	REGEN-COV 600 mg SC (N=75)	REGEN-COV 1200 mg SC (N=73)	Total (N=225)
Age (years)				
Mean (SD)	35.1 (9.97)	33.5 (9.18)	33.5 (10.88)	34.1 (10.00)
Sex, n (%)				
Male	31 (40.3%)	36 (48.0%)	35 (47.9%)	102 (45.3%)
Female	46 (59.7%	39 (52.0%)	38 (52.1%)	123 (54.7%)
Ethnicity, n (%)				
Hispanic or Latino	27 (35.1%)	30 (40.0%)	21 (28.8%)	78 (34.7%)
Not Hispanic or Latino	50 (64.9%)	44 (58.7%)	50 (68.5%)	144 (64.0%)
Not Reported	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)

ALL REGEN-COV DOSES SHOW SIMILAR CHANGE FROM BASELINE VIRAL LOAD AT EACH VISIT: IV & SC SIDE-BY-SIDE COMPARISON

Figure 14.2.2.7 Panel of Line Plots: LS Mean (+/-SE) Change from Baseline Vrial Load Side-by-Side Comparison of IV and SC (Seronegative mFAS)



CHANGE FROM BASELINE IN VIRAL LOAD SHOW COMPARABLE RESULTS BETWEEN STUDIES



REGEN-COV AS A PASSIVE VACCINE: 1200 MG SC APPEARS EFFICACIOUS

INITIAL RESULTS FROM 2069 TRIAL IN PEOPLE AT HIGH RISK OF INFECTION (DUE TO HOUSEHOLD EXPOSURE WITH "INDEX PATIENT") – Phase 3 results pending April 2021

Initial results in 409 patients (223 placebo; 186 REGEN-COV)

Reduction in infections

- **100% reduction** in symptomatic PCR-positive infections
  - 8/223 (3.6%) PBO vs. 0/186 (0%) REGEN-COV; OR 0.00 (0.00, 0.69) p<0.01
- **100% reduction** in "high virus" PCR-positive infections (>10^4)
  - 13/212 (6.1%) PBO vs. 0/179 (0%) REGEN-COV; OR 0.00 (0.00, 0.37) p<0.001
  - Of infected patients, those on PBO remained PCR-positive for an average of 2-3 weeks, while no infections lasted >1 week in those receiving REGEN-COV
- **~50% reduction** in any PCR-positive infection
  - 23/223 (10.3%) PBO vs. 10/186 (5.4%) REGEN-COV; OR 0.49 (0.20, 1.12) p<0.10

Reduction in disease burden

- **~80% reduction** in "total weeks of viral shedding"
  - Viral load >LOD; 44 weeks PBO vs. 9 weeks REGEN-COV
- **100% reduction** in "total weeks of high viral shedding"
  - Viral load >104; 22 weeks PBO vs. 0 weeks REGEN-COV
- **100% reduction** in "total symptomatic weeks"
  - 18 weeks PBO vs. 0 weeks REGEN-COV
- **Generally well tolerated** and consistent with known safety profile of REGN-COV

REGEN-COV is not authorized by the FDA for use in prophylaxis of Covid-19

LOD: level of detection

REGEN-COV REMAINS EFFECTIVE AGAINST KNOWN VARIANTS

FDA recently updated EUA Fact Sheets for all authorized antibodies†

REGEN-COV

From FDA EUA Fact Sheet for Health Care Providers

Lineage with Spike Protein Substitution	Key Substitutions Tested	Fold Reduction in Susceptibility
B.1.1.7 (UK origin)	N501Y[a]	no change[c]
B.1.351 (South Africa origin)	K417N, E484K, N501Y[b]	no change[c]
P.1 (Brazil origin)	K417T + E484K	no change[c]
B.1.427/B.1.429 (California origin)	L452R	no change[c]
B.1.526 (New York origin)[d]	E484K	no change[c]

Bamlanivimab Alone†
from FDA EUA Fact Sheet for Health Care Providers

Lineage with Spike Protein Substitution	Key Substitutions Tested[a]	Fold Reduction in Susceptibility
B.1.1.7 (UK origin)	N501Y	no change[b]
B.1.351 (South Africa origin)	E484K	>2,360[c]
P.1 (Brazil origin)	E484K	>2,360[c]
B.1.427/B.1.429 (California origin)	L452R	>1,020[c]
B.1.526 (New York origin)[d]	E484K	>2,360[c]

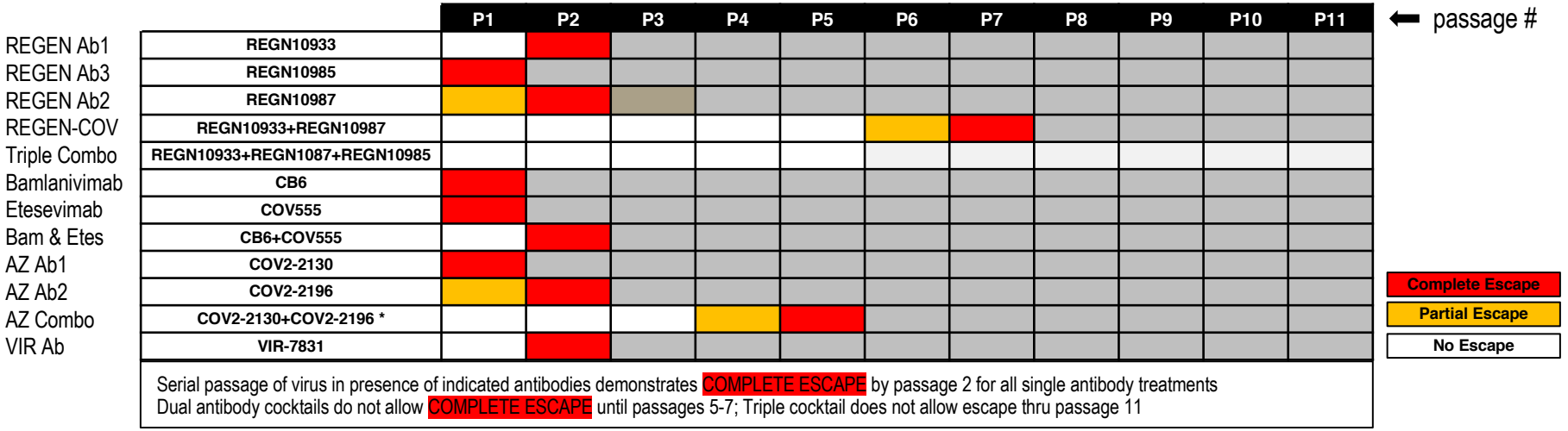
Bamlanivimab and Etesevimab Together (1:2 Molar ratio)
from FDA EUA Fact Sheet for Health Care Providers

Lineage with Spike Protein Substitution	Key Substitutions Tested[a]	Fold Reduction in Susceptibility
B.1.1.7 (UK origin)	N501Y	no change[b]
B.1.351 (South Africa origin)	K417N + E484K + N501Y	>45[c]
P.1 (Brazil origin)	K417T + E484K + N501Y	>511[c]
B.1.427/B.1.429 (California origin)	L452R	7.4
B.1.526 (New York origin)[d]	E484K	17

- As per Fact Sheets, clinical sequencing of viral isolates from patients treated with either Bam alone, or Bam+Etes, reveals outgrowth of resistant single amino acid variants, whereas variant outgrowth is not seen in sequencing from patients treated with REGEN-COV

† Bamlanivimab alone no longer being distributed in the United States due to concern about emerging variants

COCKTAILS OF "NON-COMPETING" ANTIBODIES (AGAINST TWO DISTINCT EPITOPES) SAFEGUARD AGAINST VIRAL ESCAPE IN VITRO†, IN ANIMAL MODELS (NOT SHOWN†), & IN HUMAN TRIALS



Serial passage of virus in presence of indicated antibodies demonstrates COMPLETE ESCAPE by passage 2 for all single antibody treatments
Dual antibody cocktails do not allow COMPLETE ESCAPE until passages 5-7; Triple cocktail does not allow escape thru passage 11

Treatment with all single Abs – and Bam+Etes combo of "overlapping" Abs – results in rapid selection of escape mutants (and predicts role of clinically significant emerging variants, eg, E484K)

- Sequencing demonstrates that single mutations (resulting in single amino acid changes) are sufficient for escape from every one of the single antibody treatments, as well as the Bam+Etes combo (as both antibodies bind an overlapping epitope)
  - Viruses with the single amino acid substitutions are >100-times less sensitive to Abs in neutralization assays

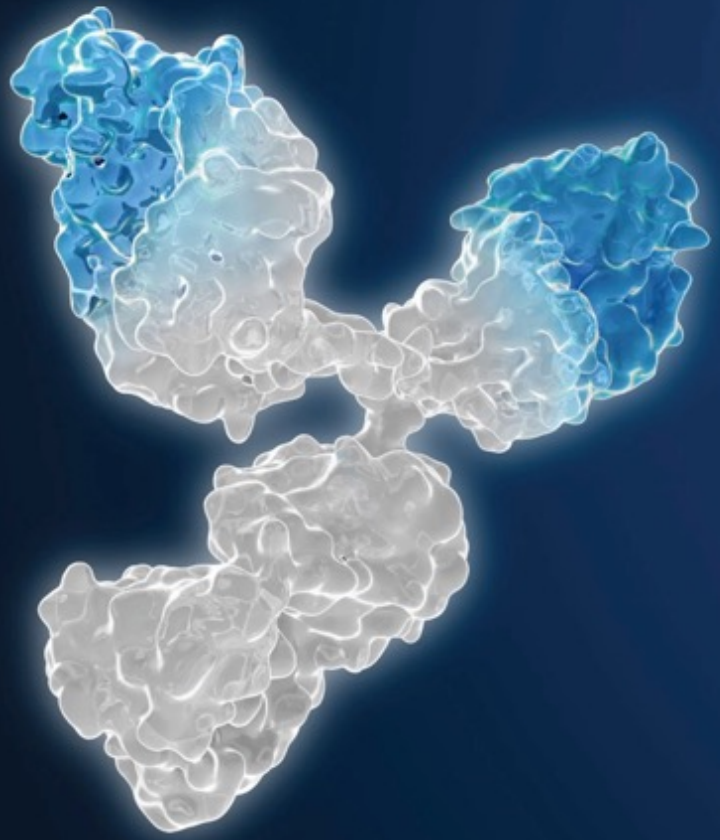
Double or triple Ab cocktails require accumulation of multiple mutations in order to escape

- Two independent mutations are required for escape from REGEN-COV cocktail as well as AZ Combo

Sequencing of clinical samples from REGN & Lilly trials confirms above findings (see FDA EUA Fact Sheets)

- Sequencing from patients treated with either Bam alone, or Bam+Etes, reveals outgrowth of resistant single aa variants, whereas variant outgrowth is not seen in sequencing from patients treated with REGEN-COV

†bioRxiv (10.1101/2021.03.10.434834) & unpublished data



SAFETY

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2067 PHASE 3: SERIOUS ADVERSE EVENTS (SAEs)/ADVERSE EVENTS OF SPECIAL INTEREST (AESIs)

ACCEPTABLE AND WELL-TOLERATED SAFETY PROFILE AND NO NEW SERIOUS SAFETY CONCERN IDENTIFIED

	PBO (N=1843)	1200 mg IV (N=827)	2400 mg IV (N=1849)	8000 mg IV (N=1012)
AESI Infusion-related reaction ≥Grade 2 thru Day 4	0	2 (0.2%)	1 (<0.1%)	3 (0.4%)
AESI Hypersensitivity reaction ≥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

- SAEs and AESIs occurred more frequently in the placebo group compared to any REGEN-COV treatment group
- No imbalance in safety between the different REGEN-COV dose groups
- No safety signal observed in safety labs (chemistry, hematology)
- More patients had TEAEs with fatal outcome in placebo group as compared to any REGEN-COV treatment group
- Very few patients experienced AESIs of IRRs and hypersensitivity reactions in REGEN-COV dose groups

2067 PHASE 3: SAEs THAT OCCURRED IN >1 PATIENT IN ANY TREATMENT GROUP, BY SYSTEM ORGAN CLASS/PREFERRED TERM

SAEs OCCURRED MORE FREQUENTLY IN THE PLACEBO GROUP AS COMPARED TO ANY REGEN-COV DOSE GROUP UP TO 8000 MG

Primary System Organ Class Preferred Term	Placebo (N=1843)	1200 mg IV (N=827)	2400 mg IV (N=1849)	8000 mg 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%)

- SAEs occurred more frequently in the placebo group as compared to any REGEN-COV dose group up to 8000 mg
  - The more frequently reported events were consistent with COVID-19 and associated complications
- Lower frequency of events in the REGEN-COV dose groups consistent with treatment benefit

2067 PHASE 3: AESIs (INFUSION RELATED REACTIONS OR HYPERSENSITIVITY REACTIONS), BY PREFERRED TERM

LOW RATES OF INFUSION RELATED REACTIONS OR HYPERSENSITIVITY REACTIONS ACROSS ALL DOSE GROUPS

Primary System Organ Class Preferred Term	Placebo (N=1843)	1200 mg IV (N=827)	2400 mg IV (N=1849)	8000 mg IV (N=1012)	Total (N=5531)
Patients with any ≥Grade 2 Infusion Related Reaction	**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 ≥Grade 2 Hypersensitivity Reaction	**1 (<0.1%)**	**0**	**1 (<0.1%)**	**0**	**2 (<0.1%)**
Urticaria	1 (<0.1%)	0	1 (<0.1%)	0	2 (<0.1%)

20145 TRIAL: IV DOSES TREATMENT EMERGENT ADVERSE EVENT (TEAE) OVERVIEW

ALL DOSES WERE WELL-TOLERATED

	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

AESIs 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

20145 TRIAL: SC DOSES TEAEs OVERVIEW

ALL DOSES WERE WELL-TOLERATED

	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

2067 PHASE 3: REGEN-COV REDUCES COVID-19-RELATED HOSPITALIZATION OR ALL-CAUSE DEATH, AND SHORTENS TIME TO SYMPTOMS RESOLUTION; 1200 MG AND 2400 MG PERFORM SIMILARLY

20145 DOSE RANGING VIROLOGIC EFFICACY STUDY: SINGLE DOSES OF 300 MG IV OR 600 MG SC SHOW SIMILAR VIROLOGIC EFFICACY TO HIGHER DOSES

2067 Outpatient clinical outcomes trial (n=4567)

- **REGEN-COV significantly reduces COVID-19-related hospitalization or all-cause death in high-risk COVID-19 patients**
  - Similar treatment effect with the two dose levels: **2400 mg vs PBO, 71.3% reduction** (1.3% vs 4.6%; p<0.0001); **1200 mg vs PBO, 70.4% reduction** (1.0% vs 3.2%; p=0.0024)
- **REGEN-COV results in faster symptoms resolution:** 2400 mg vs PBO, median 10 vs 14 days; p<0.0001; 1200 mg vs PBO, median 10 vs 14 days; p<0.0001

20145 Outpatient Dose ranging virology efficacy trial (n=803): 2400, 1200, 600 & 300 mg IV; 1200 & 600 mg SC;

- **Dose ranging study in low-risk patients (asymptomatic, or symptomatic with no risk factors): All 6 REGEN-COV dose levels tested showed significant and comparable virologic reduction thru day 7 in patients who were SARS-CoV-2 PCR+ and seronegative at baseline**

Safety (2067, n=5531; 20145, n=803): largest safety database to date for anti-SARS-CoV-2 monoclonal antibodies

- **REGEN-COV generally safe and well-tolerated; no serious safety signal, no safety dose response observed; few (<0.1%) IRRs / hypersensitivity reactions**
  - In 2067 outcomes study, SAEs (including fatal events) more frequent in the PBO group compared to REGEN-COV dose groups (4.0% PBO vs 1.4% combined REGEN-COV)
  - In 20145 dose-ranging study, no fatalities, 2 SAEs, both assessed as not related to COVID-19 or study drug

In a Phase 3 trial in 4567 high-risk patients, REGEN-COV significantly reduced COVID-19 hospitalization or all-cause death, and shortened time to symptoms resolution by 4 days, confirming clinical benefit seen in Phase 1/2

In the dose-ranging virologic efficacy study in 803 low-risk patients, REGEN-COV significantly and substantially reduced viral load across all dose levels tested, down to as low as single doses of 300 mg IV or 600 mg SC

REGEN-COV has an acceptable safety profile at all dose levels; no safety signal observed in outpatient studies

1-2M INDIVIDUALS ARE STILL INFECTED EACH MONTH IN THE U.S. ALONE, RESULTING IN TENS OF THOUSANDS OF DEATHS: MEDICAL IMPERATIVE TO TREAT EACH HIGH-RISK PATIENT

- We now have compelling data confirming the profound anti-viral activity of the REGEN-COV Antibody Cocktail, as well as its profound ability to protect high-risk patients from progressing to Hospitalization or Death (as well as its ability to decrease symptom duration by ~4 days, on average)
- The REGEN-COV Antibody Cocktail retains its potency against the most dangerous and concerning emerging variants
- We now have the supply chain to treat about 0.5M patients a month – a large proportion if not all high-risk patients (currently only ~10,000 patients are treated each month, resulting in unnecessary and devastating loss of life)

It's time to raise awareness and renew confidence in the "monoclonal antibody" approach, and widely inform about the value of making sure we treat every single high-risk patient in the U.S., as keeping patients from progressing to severe COVID-19 should save many lives

- ❖ Tens of thousands of lives at stake every month
- ❖ Such widespread treatment should also slow the spread of concerning variants, that may ultimately otherwise undermine natural- and vaccine-immunity

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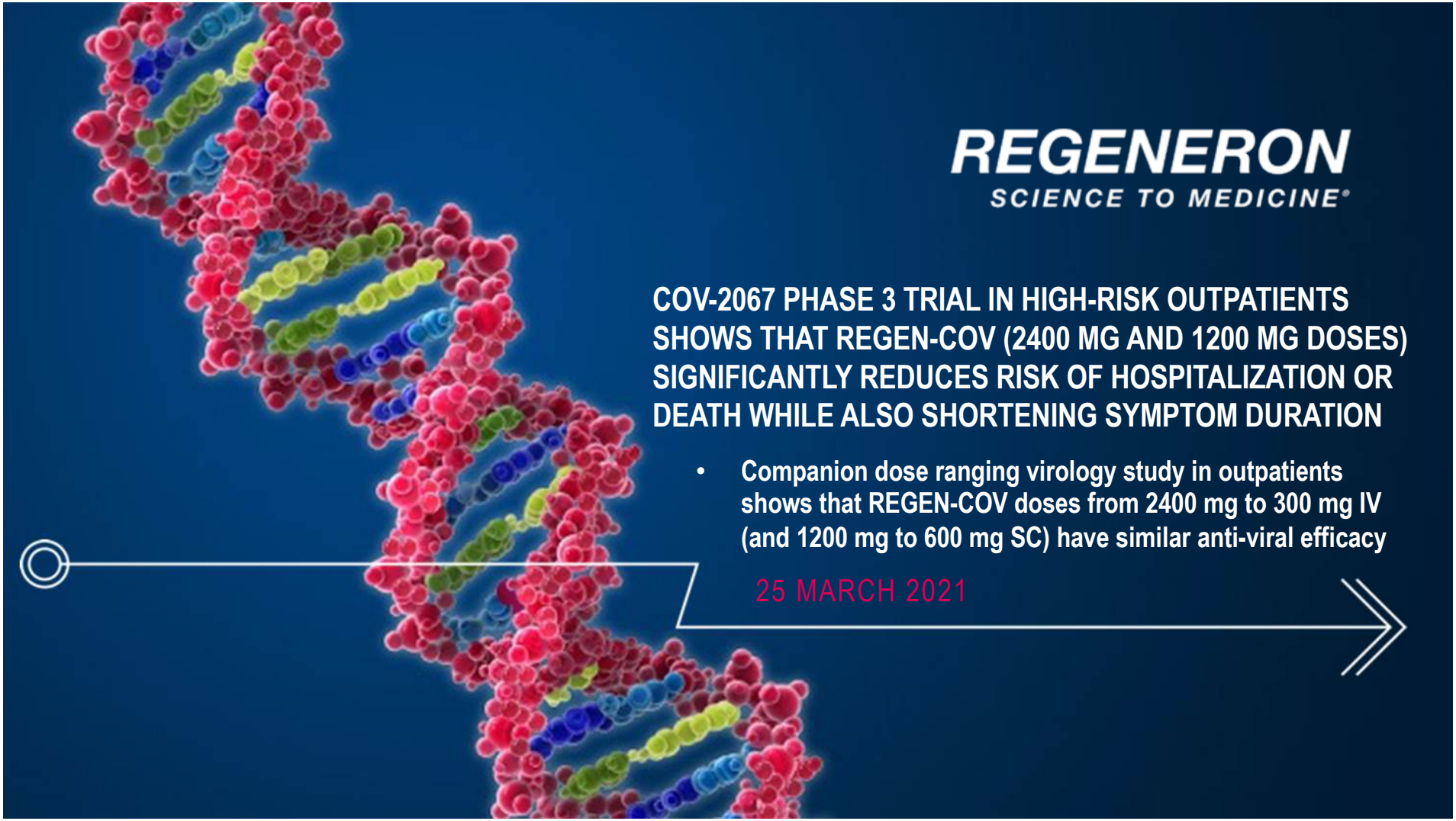
REGENERON
SCIENCE TO MEDICINE®
COV-2067 PHASE 3 TRIAL IN HIGH-RISK OUTPATIENTS SHOWS THAT REGEN-COV (2400 MG AND 1200 MG DOSES) SIGNIFICANTLY REDUCES RISK OF HOSPITALIZATION OR DEATH WHILE ALSO SHORTENING SYMPTOM DURATION
• Companion dose ranging virology study in outpatients shows that REGEN-COV doses from 2400 mg to 300 mg IV (and 1200 mg to 600 mg SC) have similar anti-viral efficacy
25 MARCH 2021