
FIGHT
COVID-19
With Neutralizing mAbs
If you still need to complete your pretest, please access
it using the link on the screen or the link in chat.

FACULTY AND DISCLOSURES

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No relevant financial relationships to disclose

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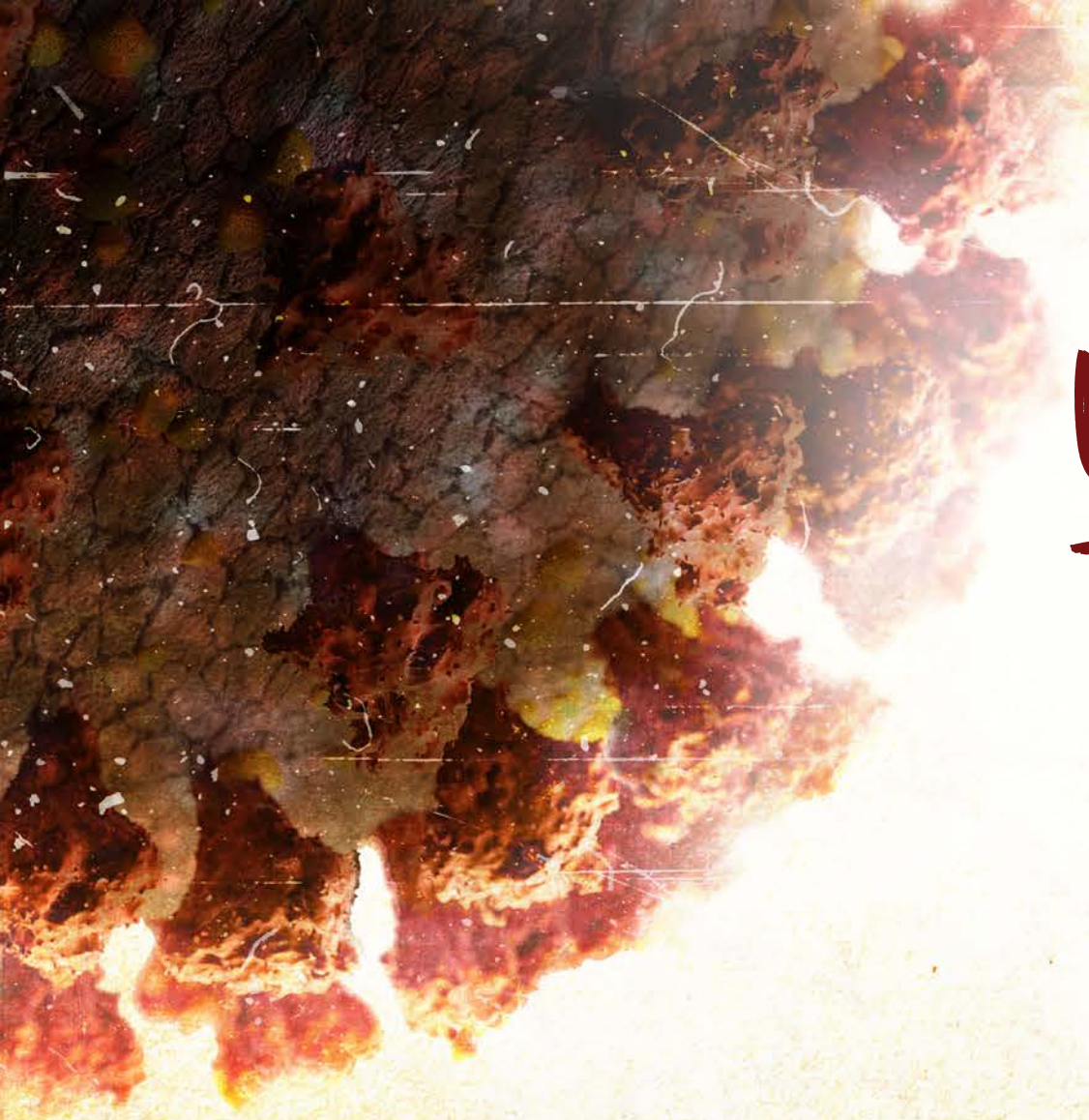
Submit your questions anytime using chat

Polling questions

Text ReachMD to 22333
Text in your answers!

OR

Go to PollEv.com
Enter **ReachMD**



UPDATES IN CLINICAL TRIAL DATA

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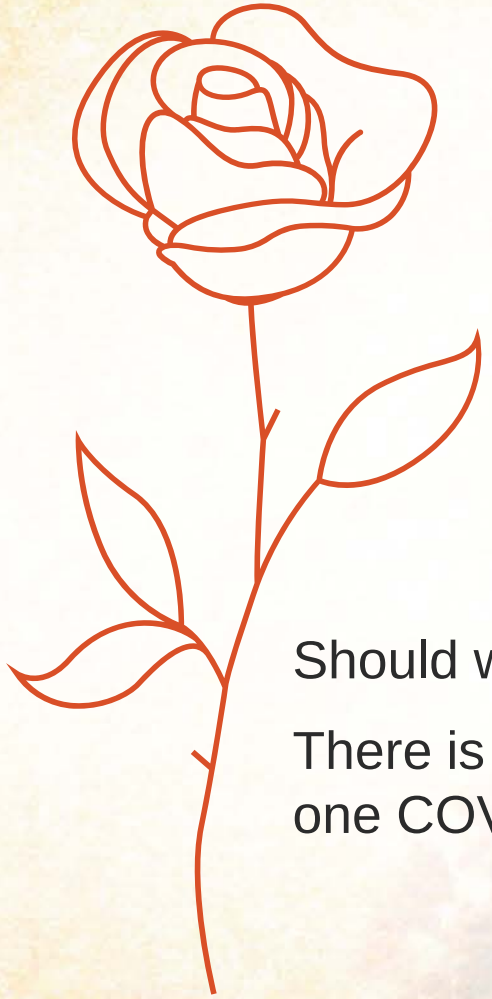
COVID-19: THE NAME CAN DECEIVE YOU



What's in a name?

That which we call
a rose
By any other name
would smell as sweet.

—William Shakespeare

NOT THE SAME FOR EVERYONE

- Asymptomatic
- Mildly symptomatic
- Hospitalized
- Dead

Should we have called it COVID-19(a), COVID-19(b), COVID-19(c)?

There is more than one type of cancer; there is more than one COVID-19 response…virus *and* host.

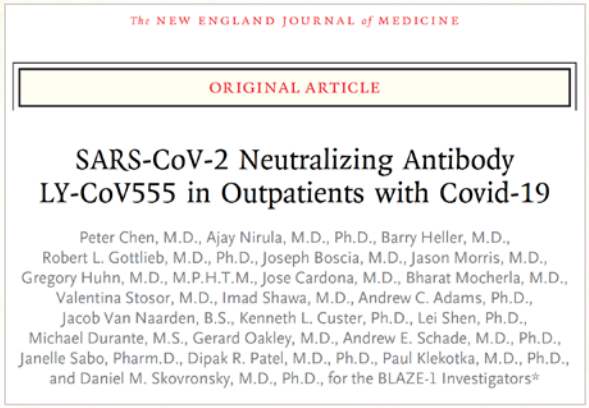
Wang X, et al. *Chest*. 2021.

3 NEUTRALIZING mAb THERAPIES HAVE RECEIVED EUA

1 Bamlanivimab[1]

November 9, 2020

March 25, 2021: Distribution halted as a monotherapy[4]



The NEW ENGLAND JOURNAL of MEDICINE

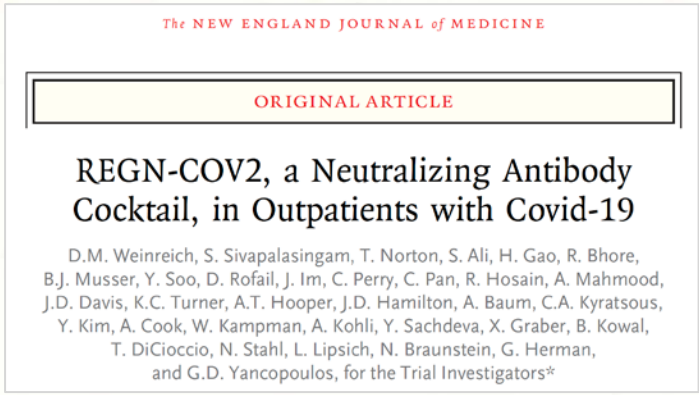
ORIGINAL ARTICLE

SARS-CoV-2 Neutralizing Antibody LY-CoV555 in Outpatients with Covid-19

Peter Chen, M.D., Ajay Nirula, M.D., Ph.D., Barry Heller, M.D., Robert L. Gottlieb, M.D., Ph.D., Joseph Boscia, M.D., Jason Morris, M.D., Gregory Huhn, M.D., M.P.H.T.M., Jose Cardona, M.D., Bharat Mocherla, M.D., Valentina Stosor, M.D., Imad Shawa, M.D., Andrew C. Adams, Ph.D., Jacob Van Naarden, B.S., Kenneth L. Custer, Ph.D., Lei Shen, Ph.D., Michael Durante, M.S., Gerard Oakley, M.D., Andrew E. Schade, M.D., Ph.D., Janelle Sabo, Pharm.D., Dipak R. Patel, M.D., Ph.D., Paul Klekotka, M.D., Ph.D., and Daniel M. Skovronsky, M.D., Ph.D., for the BLAZE-1 Investigators*

2 Casirivimab/imdevimab[2]

November 21, 2020



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

REGN-COV2, a Neutralizing Antibody Cocktail, in Outpatients with Covid-19

D.M. Weinreich, S. Sivapalasingam, T. Norton, S. Ali, H. Gao, R. Bhore, B.J. Musser, Y. Soo, D. Rofail, J. Im, C. Perry, C. Pan, R. Hosain, A. Mahmood, J.D. Davis, K.C. Turner, A.T. Hooper, J.D. Hamilton, A. Baum, C.A. Kyratsous, Y. Kim, A. Cook, W. Kampman, A. Kohli, Y. Sachdeva, X. Graber, B. Kowal, T. DiCioccio, N. Stahl, L. Lipsich, N. Braunstein, G. Herman, and G.D. Yancopoulos, for the Trial Investigators*

3 Bamlanivimab/etesevimab[3]

February 9, 2021

JAMA | Original Investigation

Effect of Bamlanivimab as Monotherapy or in Combination With Etesevimab on Viral Load in Patients With Mild to Moderate COVID-19

A Randomized Clinical Trial

Robert L. Gottlieb, MD, PhD; Ajay Nirula, MD, PhD; Peter Chen, MD; Joseph Boscia, MD; Barry Heller, MD; Jason Morris, MD, MS; Gregory Huhn, MD, MPHTM; Jose Cardona, MD; Bharat Mocherla, MD; Valentina Stosor, MD; Imad Shawa, MD; Princy Kumar, MD; Andrew C. Adams, PhD; Jacob Van Naarden, BS; Kenneth L. Custer, PhD; Michael Durante, MS; Gerard Oakley, MD; Andrew E. Schade, MD, PhD; Timothy R. Holzer, PhD; Philip J. Ebert, PhD; Richard E. Higgs, PhD; Nicole L. Kallewaard, PhD; Janelle Sabo, PharmD; Dipak R. Patel, MD, PhD; Paul Klekotka, MD, PhD; Lei Shen, PhD; Daniel M. Skovronsky, MD, PhD

mAB=monoclonal antibodies. EUA=emergency use authorization.

1. Chen P, et al. *N Engl J Med*. 2021;384(3):229-237. 2. Gottlieb RL, et al. *JAMA*. 2021. 3. Weinreich DM, et al. *N Engl J Med*. 2021;384(3):238-251.
4. https://www.genengnews.com/news/u-s-halts-distribution-of-lillys-bamlanivimab-monotherapy-citing-sars-cov-2-variant-resistance/. Accessed March 26, 2021.

STRATEGY OF USING A COMBINATION THERAPY

Combinations of mAbs together may be more effective

- Limit escape
- Help address variants

Spike Variant	Bamlanivimab		Etesevimab	
	IC_{50} µg/mL (95% CI)	Fold-Shift in IC_{50}	IC_{50} µg/mL (95% CI)	Fold-Shift in IC_{50}
Wuhan*	0.01 (0.01, 0.02)	1	0.13 (0.07, 0.41)	1
E484K	>1	>100	0.57 (0.36, 1.11)	4.4
E484Q	>1	>100	0.17 (0.10, 0.36)	1.4
F4905	>1	>100	0.1 (0.04, >2)†	0.8
S494P	>1	>100	0.07 (0.03, >2)†	0.5

*SARS-CoV-2 S Genbank MN908947.3. †CI cannot be calculated.

CI=confidence interval. E=glutamate. F=phenylalanine. IC_{50}=concentration inhibiting maximal activity by 50%. K=lysine. P=proline. Q=glutamine. S=serine. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

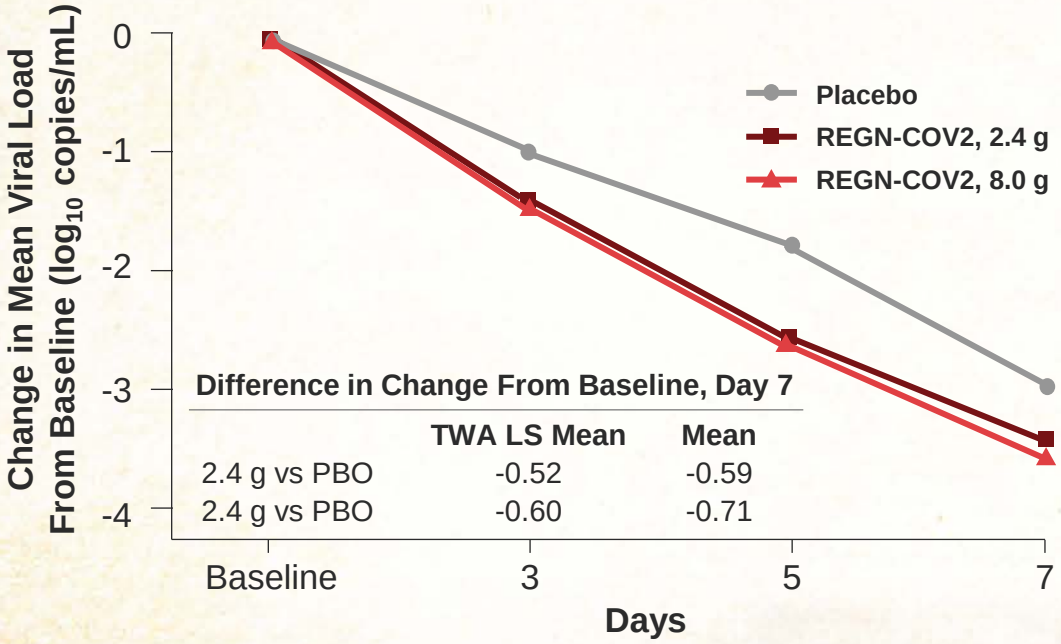
Gottlieb RL et al. *JAMA*. 2021;325(7):632-644.

STUDY OF CASIRIVIMAB+IMDEVIMAB TOGETHER

NEUTRALIZING mAb MOST EFFECTIVE EARLY (SERONEGATIVE) AND WITH HIGHER VIRAL TITERS AT BASELINE

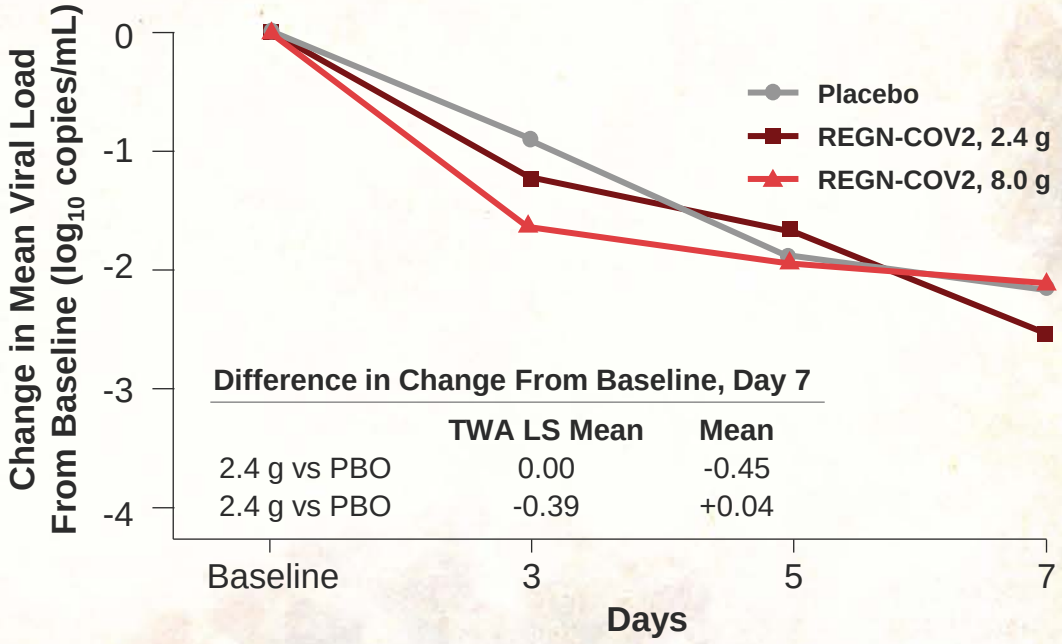
VIRAL LOAD OVER TIME ACCORDING TO BASELINE ANTIBODY STATUS

Serum Antibody-Negative



Number at risk				
Placebo	30	23	28	28
REGN-COV2, 2.4 g	35	32	34	34
REGN-COV2, 8.0 g	36	34	35	35

Serum Antibody-Positive



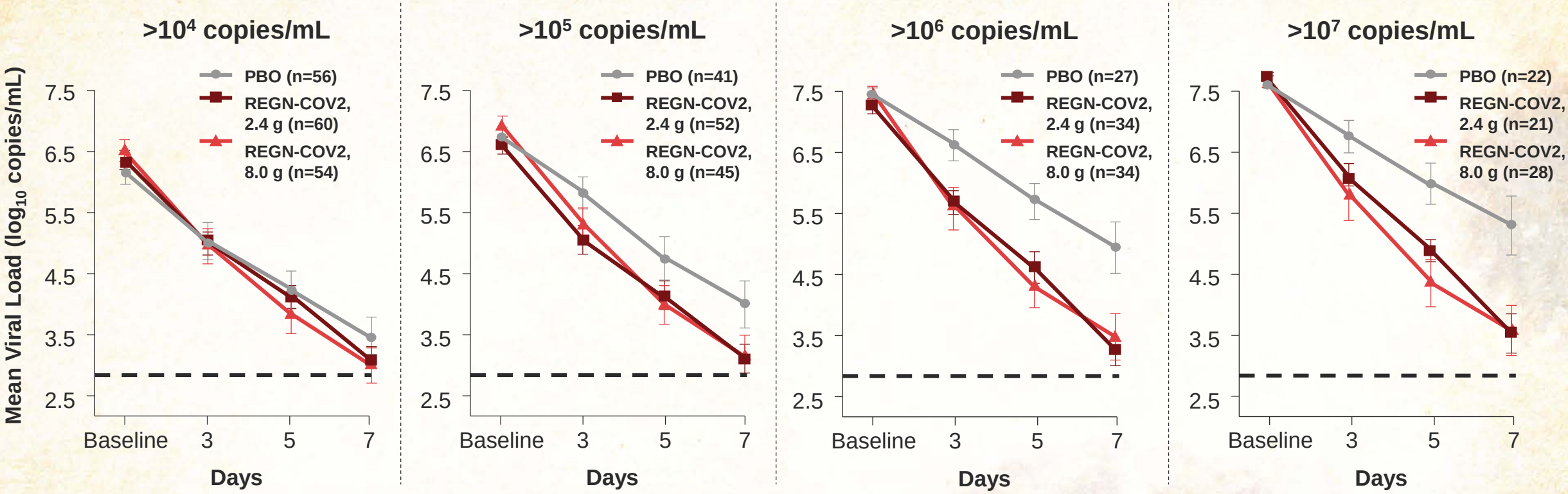
Number at risk				
Placebo	38	35	37	37
REGN-COV2, 2.4 g	27	26	27	27
REGN-COV2, 8.0 g	29	38	29	29

PBO=placebo. TWA=time-weighted average. LS=least squares.

Weinreich DM, et al. *N Engl J Med*. 2020.

CASIRIVIMAB/IMDEVIMAB: VIRAL LOAD

OVER TIME ACCORDING TO BASELINE VIRAL LOAD CATEGORY

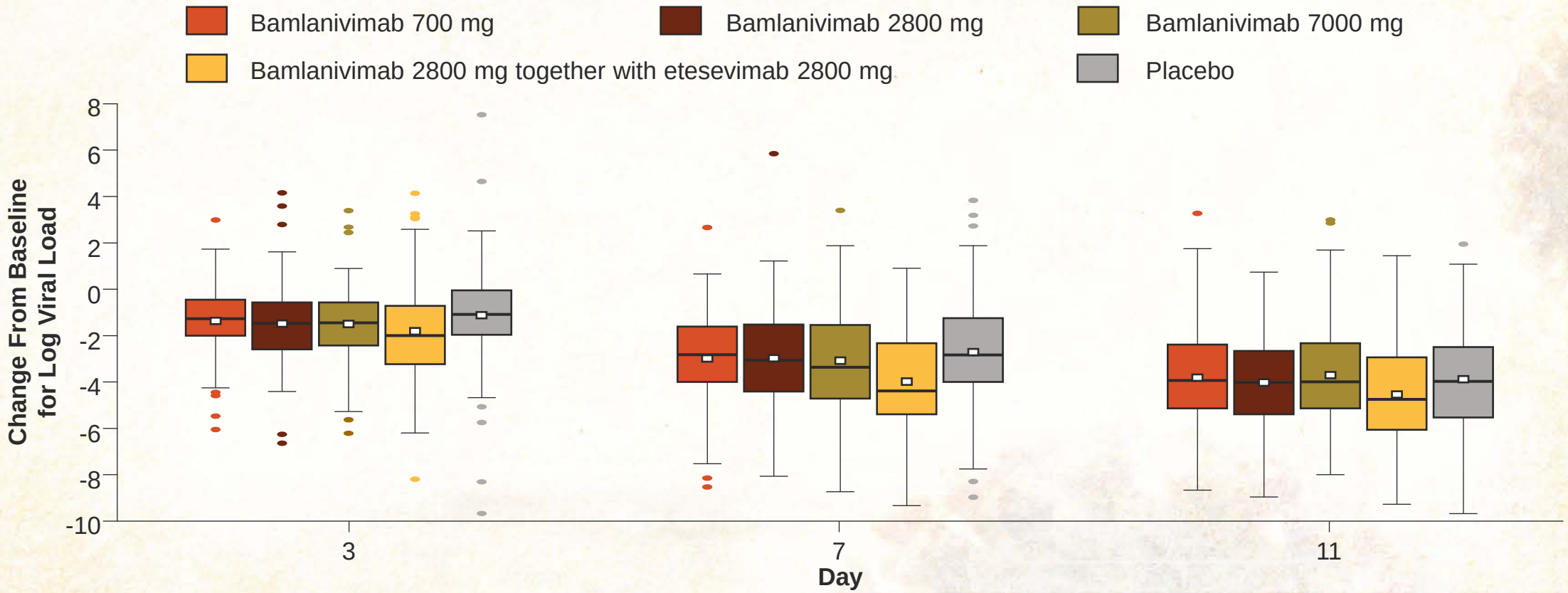


Difference in Change From Baseline, Day 7

	>10⁴ copies/mL		>10⁵ copies/mL		>10⁶ copies/mL		>10⁷ copies/mL	
	TWA LS Mean	Mean	TWA LS Mean	Mean	TWA LS Mean	Mean	TWA LS Mean	Mean
2.4 g vs PBO	-0.36	-0.64	-0.59	-0.83	-0.81	-1.46	-1.03	-1.84
2.4 g vs PBO	-0.36	-0.64	-0.75	-1.12	-1.14	-1.54	-1.32	-1.75

STUDY LIMITATIONS: No formal hypothesis testing was performed to control type I error and the analyses according to baseline viral load were post hoc.

BAMLANIVIMAB/ETESEVIMAB: LOG VIRAL LOAD



STUDY LIMITATIONS: The study population was small; only 1 combination dose was tested; optimal timeline for detecting the effect of treatment on the immune response may have been earlier than day 11.

Gottlieb RL, et al. *JAMA*. 2021.

EARLY IDENTIFICATION AND TREATMENT ARE KEY

The CDC Recommends Early Use of Antivirals for Influenza[1]

HYPOTHESIS

Early (outpatient) COVID-19 is virally driven and susceptible to antiviral management

Late (inpatient) COVID-19 is virally uncoupled

CLINICAL TRIALS

In clinical trials of neutralizing mAbs, treatment was given early and in outpatient settings

- BLAZE (bamlanivimab): ≤3 days from first positive test[2]
- REGN-COV2 trial (casirivimab/imdevimab): ≤7 days from first symptom[3]

LATE TREATMENT

If severe disease occurs, late treatment does not help[4]

1. https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm. Accessed March 23, 2021. 2. Chen P, et al. *N Engl J Med*. 2021;384(3):229-237.
3. Weinreich DM, et al. *N Engl J Med*. 2021;384(3):238-251. 4. Lundgren JD, et al. *N Engl J Med*. 2020.

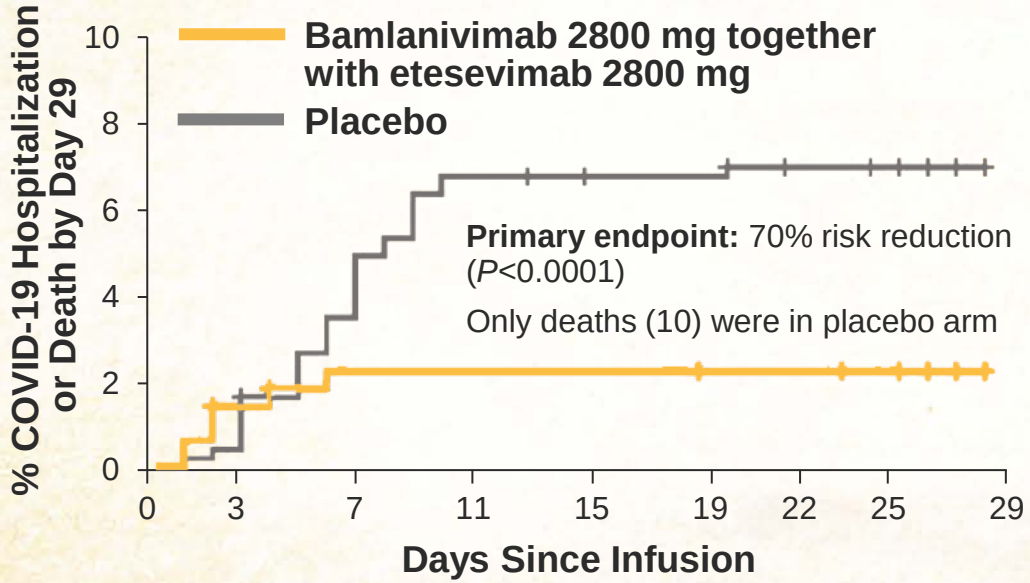
BLAZE-1 PHASE 3 DATA (PUBLICATION PENDING)

Randomized 1:1 (active:placebo), blinded data

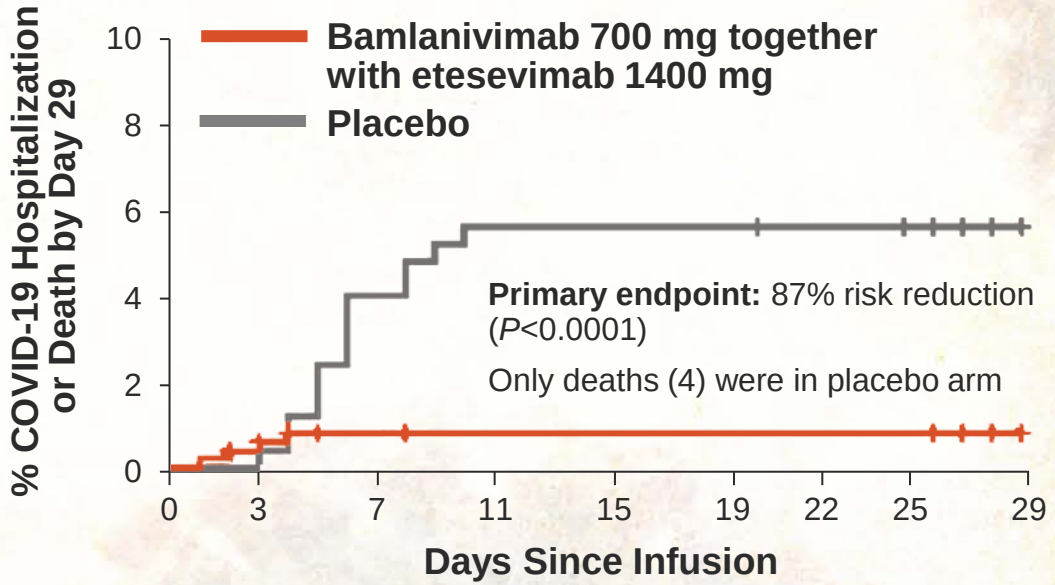
High-risk (essentially EUA) populations
- Note: phase 2 study included any adult

Pregnancy was excluded in trials
- Although the EUA allows pregnancy as risk factor

NEUTRALIZING mAb BAMLANIVIMAB + ETESEVIMAB REPRODUCIBLY DECREASED THE PRIMARY ENDPOINT, COVID-19–RELATED HOSPITALIZATION AND ALL-CAUSE DEATH



Treatment	Patients	Events (%)
Bamlanivimab 2800 mg together with etesevimab 2800 mg	518	11 (2.1%)
Placebo	517	34 (6.6%)

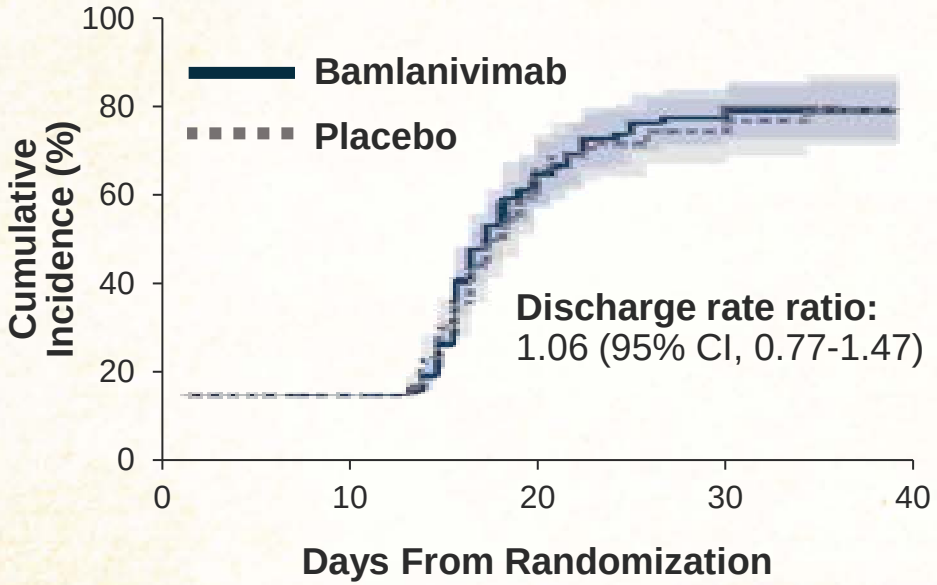


Treatment	Patients	Events (%)
Bamlanivimab 700 mg together with etesevimab 1400 mg	511	4 (0.8%)
Placebo	258	14 (5.4%)

1. (Figures) Adapted by https://www.prnewswire.com/news-releases/lillys-bamlanivimab-and-etesevimab-together-reduced-hospitalizations-and-death-in-phase-3-trial-for-early-covid-19-301243984.html. Accessed on March 25, 2021. 2. https://clinicaltrials.gov/ct2/show/NCT04427501. Accessed on March 25, 2021.

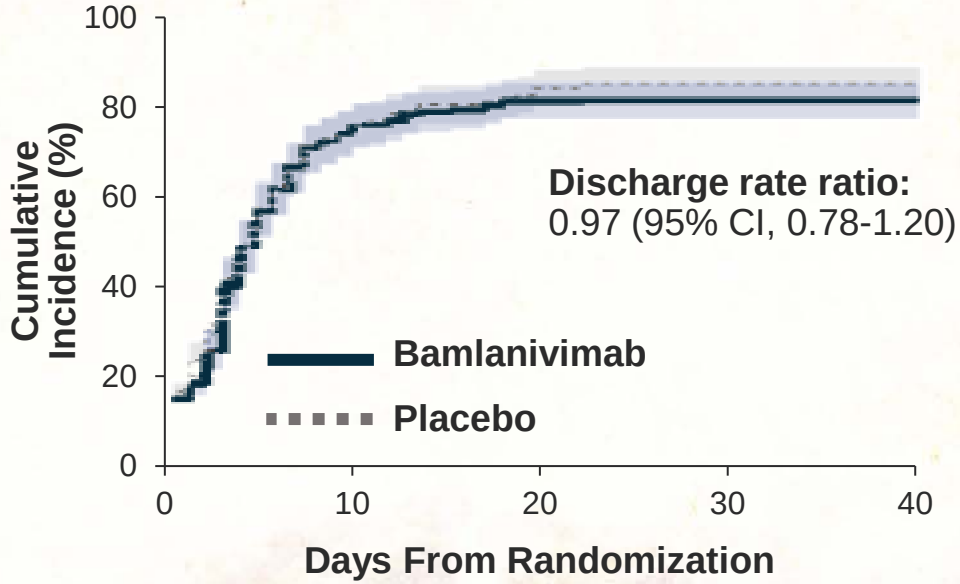
NEUTRALIZING mAbs WERE NOT BENEFICIAL IN HOSPITALIZED PATIENTS

TIME TO SUSTAINED RECOVERY



Number at risk					
Bamlanivimab	87	86	41	9	3
Placebo	81	81	41	10	4

TIME TO HOSPITAL DISCHARGE



Number at risk					
Bamlanivimab	163	38	17	6	3
Placebo	151	36	13	6	4

Lundgren JD, et al. *N Engl J Med*. 2020.

CONCLUSION: CLINICAL TRIAL DATA

May reduce hospitalization or ED visits when given within 72 hours of diagnosis.

Have not been demonstrated to have efficacy in hospitalized patients.

Have more dramatic effects in higher risk patients and in those who do not have an early antibody response.

Appear to be safe.

POLLING QUESTION

A 57-year-old perimenopausal female with BMI 34.9 calls your office to report 5 days of chills without fever and associated myalgias but absent cough.

She followed your advice and bought a pulse oximeter last year “just in case.”

SpO_2 is 95%.

Rapid SARS-CoV-2 direct antigen test was positive at a drive-through test center.

She asks you to call her in a prescription for ivermectin.

POLLING QUESTION

What do you recommend?

A. Ivermectin and strict quarantine

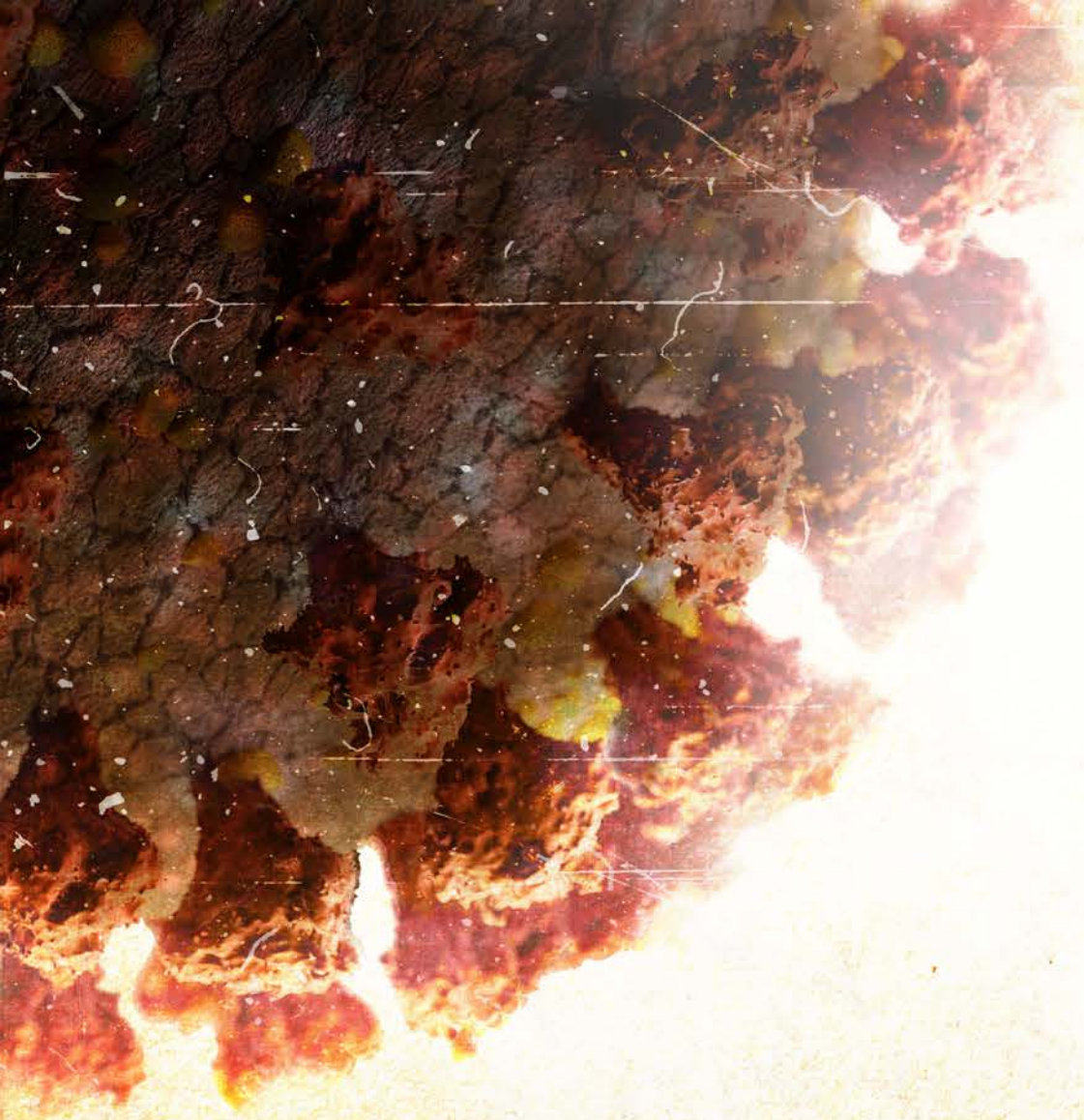
B. Social isolation and keep checking her pulse ox; hospitalization if SpO_2 ≤90%

C. Neutralizing mAb therapy if she develops a fever or cough; counsel her she is not sick enough to qualify yet

D. It is too late for neutralizing mAb therapy as it has been over 48 hours since her symptoms began

E. Arrange neutralizing mAb therapy with bamlanivimab together with etesevimab the following day

F. Repeat test, as COVID-19 diagnosis requires PCR rather than direct antigen test



EUA CRITERIA AND PRACTICAL CONSIDERATIONS

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The University of Alabama at Birmingham
School of Medicine
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QUALIFYING FOR A NEUTRALIZING mAb

Outpatients With Mild-Moderate COVID-19 Who Do Not Require Oxygen (or Increase in Baseline Oxygen Flow) but Who Are at High Risk for Progression to Severe Disease

Any ≥1 of the following:


≥65 years old


BMI ≥35


Chronic kidney disease


Diabetes


Immunosuppressive disease


Immunosuppressive treatment


≥55 years old with ≥1 of the following:

- Cardiovascular disease
- Hypertension
- Chronic obstructive pulmonary disease
- Chronic respiratory disease


Age 12-17 years old and ≥1 of the following:

- BMI ≥85th percentile for age/gender
- Sickle cell disease
- Congenital heart disease
- Acquired heart disease
- Neurodevelopmental disorders (eg, cerebral palsy)
- Medical-related technological dependence (eg, gastrostomy)
- Chronic respiratory disease requiring daily medication for control (eg, asthma)

Because no neutralizing monoclonal antibody is officially FDA-approved, consent from the patient or authorized designee must be obtained before use.

1. *JAMA*.2021;325(9):880-81. 2. Pallotta AM, et al. *Cleve Clin J Med*. 2021.

CONSIDERATIONS FOR TREATMENT ADMINISTRATION

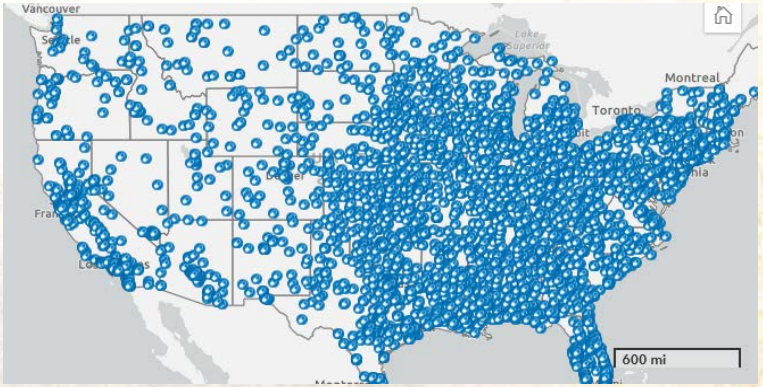
	Casirivimab/Imdevimab	Bamlanivimab/Etesevimab
Target site	Nonoverlapping epitopes of RBD SARS-CoV-2 spike protein Unmodified in Fc region	Overlapping epitopes of RBD Etesevimab—RBD of SARS-CoV-2 spike protein in the Fc Region (L234A. L235A)
Dose	1200 mg/1200 mg administered concurrently	700 mg/1400 mg
Pregnancy	Human Immunoglobulin G (IgG) antibodies. No data in pregnancy but use of IgG products not usually withheld. Should be given to a pregnant woman who meets criteria	
Pediatrics	American Academy of Pediatrics recommends against routine use, including those in FDA EUA criteria due to lack of data in pediatrics and conflicting evidence on EUA criteria increasing risk of severe COVID-19 in pediatrics Considered on a case-by-case basis—more data on those ≥16 years old	
Guideline recommendations	Insufficient data for or against use	Recommended by NIH Guidelines

Fc=fragment crystallizable. RBD=receptor binding domain.

1. COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at https://www.covid19treatmentguidelines.nih.gov/. Accessed March 14, 2021. 2. Bhimraj A, et al. *Clin Infect Dis*. 2020. 3. Wolf J, et al. *J Pediatric Infect Dis Soc*. 2021.

LOCATING mAb TREATMENT CENTERS

- Infusions are authorized in a variety of settings (eg, clinics, emergency departments, outpatient health centers and surgical centers, jails, nursing homes, and more)
- Many health systems have integrated clinics into their own infusion centers
- HHS Therapeutics distribution website
  - For bamlanivimab/etesevimab and casirivimab/imdevimab
  - Map and site information created using shipment data from distributors
  - Does not include smaller locations that receive ≤5 courses of treatment
  - Available: https://protect-public.hhs.gov/pages/therapeutics-distribution#distribution-locations
- National Infusion Center Association
  - Provides list of infusion centers administering antibody treatment based on geography
  - No guarantee site has allocation
  - Sponsored by pharmaceutical companies
- Ordering antibody therapies directly from wholesaler (AmerisourceBergen)



1. (Figure) HHS Protect Public Data Hub. Therapeutics Distribution Locations. Available: https://protect-public.hhs.gov/pages/therapeutics-distribution#distribution-locations Accessed March 14, 2021. 2. National Infusion Center Association. COVID-19 Antibody Therapy Locator. Available: https://covid.infusioncenter.org/ Accessed March 14, 2021. 3. Assistant Secretary for Prepardedness and response. Overview of direct order process for COVID-19 Therapeutics. Available. https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/Overview%20of%20direct%20order%20process%20Fact%20Sheet-508.pdf. Accessed March 14, 2021.

THE PREPARATION AND ADMINISTRATION PROCESS

VIALS ARE STORED IN REFRIGERATOR

- Allow 20 minutes to come to room temperature before preparation

DRUG FROM VIALS ADDED TO 250 mL 0.9% NaCl

- **Casirivimab/imdevimab**: 2 11.1 mL vials, 10 mL per vial injected into the same infusion bag for total volume of 250 mL
  - Important to remove 20 mL from 0.9% NaCl bag before adding antibodies
- **Bamlanivimab/etesevimab**: one 20 mL vial bamlanivimab and 2 20 mL vials etesevimab for total volume of 310 mL
- Invert bags 10 times to mix

ADMINISTRATION

- Via IV pump or gravity using 0.2 or 0.22 micron filter
  - Casirivimab/imdevimab over 60 minutes
  - Bamlanivimab/etesevimab over 21-60 minutes depending on concentration
- Follow infusion with 0.9% NaCl flush to ensure complete dose
- May consider longer infusion times in patients with chronic heart failure or chronic kidney disease
- Consider prolonging infusion time in patients with non-severe infusion-related reactions
- In patients <50 kg, bamlanivimab/etesevimab should be given over 70 minutes

STABILITY OF PREPARED INFUSION

- Bamlanivimab/etesevimab: refrigerate up to 24 hours and room temperature up to 7 hours
- Casirivimab/imdevimab: refrigerate up to 36 hours and room temperature up to 5 hours
- Stability time includes infusion time

Prepare infusion only once patient arrives and has IV access

- For administration in long-term care or other institutional facilities: may prepare in advance

Guide patient to room at designated infusion time

- Keep door closed
- Patient and all personnel wear PPE
- Restrict patient movement in facility

Monitor patient's vital signs before infusion starts and every 15 minutes throughout infusion and 1-hour monitoring period

1. COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at https://www.covid19treatmentguidelines.nih.gov/. Accessed March 14, 2021. 2. Bhimraj A, et al. Clin Infect Dis. 2020. 3. https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/COVID-Therapeutics-playbook_25Feb2021.pdf. Accessed March 14, 2021. 4. https://www.fda.gov/media/145802/download. Accessed March 14, 2021.

Reminder

Submit questions for faculty response

Prepare for polling questions by texting
ReachMD to 22333

WHAT TO MONITOR FOR DURING AND AFTER INFUSION ADMINISTRATION

COMMON ADVERSE EFFECTS

All
- Nausea, bleeding, bruising, soreness, swelling at injection site

Bamlanivimab/etesevimab
- Dizziness, itching, rash

Casirivimab/imdevimab
- Vomiting hyperglycemia, pneumonia

RISK OF SEVERE ADVERSE EFFECTS

Anaphylaxis

Infusion-related reactions

Clinical worsening after antibody administration
- Fever, hypoxia, increased respiratory difficulty, arrhythmias, abnormal heart rate, fatigue, altered mental status
- Unclear if these are related to drug or COVID-19

Additional safety information will emerge with increased use in practice

Many patients tolerate infusions well
"…was surprised at how easy it was. I watched Netflix on my phone and relaxed while the infusion was taking place."

All serious adverse effects and medication errors should be reported within 7 calendar days
- To Food and Drug Administration MedWatch
- To manufacturer

1. https://www.fda.gov/media/143892/download. Accessed March 14, 2021. 2. https://www.fda.gov/media/145802/download. Accessed March 14, 2021.
3. https://thedacare.org/news-and-events/symptoms-and-conditions/patient-shares-experience-receiving-antibody-infusion/. Accessed March 14, 2021.

POLLING QUESTION

To date, what has been your biggest challenge in using or recommending a neutralizing mAb therapy?

A. Understanding what patients would qualify for treatment
B. Locating where patients could receive the therapy
C. Trying to find balance goal of preventing COVID-19 disease progression with vaccination efforts
D. Discerning the benefit of therapy vs the risk of adverse effects

ANTIBODY TREATMENT AND COVID-19 VACCINATION

Not studied

In theory, neutralizing mAbs could reduce body's immune response to SARS-CoV-2 vaccine

Fully or partially vaccinated patients who develop COVID-19 can still receive antibody treatment

Patients who received 1 of 2 vaccine doses should delay the second dose for 3 months after treatment

The vaccine series does NOT have to be restarted

Unvaccinated patients should wait at least 90 days after antibody infusion before receiving vaccine

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fpfizer%2Fclinical-considerations.html. Accessed March 14, 2021.

RE-EXPOSURE TO NEUTRALIZING mAbs

Potential Reasons

Use of antibody therapy may theoretically attenuate endogenous immune response—patients may be more susceptible to SARS-CoV-2 reinfection

Administering a Second Dose of Neutralizing mAbs

No data or case reports

Half-life of neutralizing mAbs is approximately 3-4 weeks

May need to consider if infection due to certain SARS-CoV-2 variants

Consideration on a case-by-case basis

https://www.idsociety.org/globalassets/idsa/media/clinician-call-slides--qa/1-30-clinician-call-qa-dsw.pdf. Accessed March 14, 2021.

INSTITUTIONAL EXAMPLE

Tesha Seabra, MSN, RN
Associate Director, Department of Medicine
Cedars-Sinai Medical Center
Los Angeles, California

GOALS

1.  Target high-risk patients

2.  Reduce the rate of hospitalizations

3.  Increase the rate of survival

NEUTRALIZING mAb APPOINTMENTS

Appointments	Occurrences
Total volume	**783**
Total scheduled/infused	414
Total not scheduled/infused	369
Did not meet criteria	315
Self cancellations	23
Referred to other agency (home health)	12
Cancellations due to infusion administered in other facility	11
Cancellations due to hospital admission (Emergency Department)	7
Patient expired prior to infusion	1

OUTSIDE REFERRALS

Increase demand to support of nursing homes, rehabilitation facilities, and home care infusions

- Patient unable to ambulate
- Dementia
- Needed caregiver

Case management team involvement to provide adequate referrals

CASE SCENARIO

Rose is an 88-year-old patient with a history of CAD, DM, and HTN.

She tested positive for COVID-19 and her doctor entered an order for a neutralizing mAb therapy.

The scheduler calls for her come in for a same-day appointment.

The patient is HOH and seemed slightly confused on the phone.

She passed the phone to her daughter who told the scheduler that both her parents have COVID-19 and that her dad is much sicker than her mom.

However, since they do have COVID-19, the daughter acknowledges that her parents should quarantine for 10-14 days, and then she will call back and schedule for the infusion.

CAD=coronary artery disease. DM=diabetes mellitus. HTN=hypertension. HOH=hard-of-hearing.

POLLING QUESTION

The scheduler

- Agrees with the daughter and tells her to call back in 10-14 days after quarantine
- Educates the daughter that the infusion has to occur within 10 days of symptom onset or positive test
- Tells the daughter that her parents do not meet criteria for neutralizing mAb therapy
- Tells the daughter to call her mother’s doctor and change the order to a later date after self quarantine
- Tells the daughter that if patients have mild symptoms, they shouldn’t need a neutralizing mAb therapy

CASE SCENARIO (CONT.)

The daughter understands, but now tells the scheduler that we should have received the order for both her parents.

We tell her that at this time we only have the order for the mom and that we have an opening for the afternoon.

She asks if her dad can take the mother's spot since he is sicker and not doing well.

The dad 91 years old with a history of HTN and lung cancer in the past.

He had photodynamic therapy 2 years ago and is currently in remission.

We call pharmacy and are informed that the order for the dad was just approved.

The problem is that we only have 1 spot left for today.

POLLING QUESTION

How do we proceed?

- Schedule the mom because her order was received first
- Schedule the dad since he’s sicker
- Schedule both at the same time in the same room
- Schedule dad for the following day
- Tell the daughter to take dad to urgent care or ED

CASE SCENARIO (CONT.)

Both husband and wife are placed in the same room, and they are happy to be together.

While starting the IV on the wife, the nurse notices that she is diaphoretic, and she states that she feels lightheaded.

When checking VS, HR 40s and SBP 70s.

The patient has a 10-second LOC.

We recheck the VS and her HR and BP are back to baseline.

She doesn’t know what happened; she feels weak but otherwise ok.

POLLING QUESTION

How should the nurse proceed?

A. Call the physician and get an order for a blood sugar check
B. Call the crisis team and send the patient to ED
C. Cancel the infusion and send the patient home
D. Draw labs and check an EKG
E. Do nothing and proceed with the infusion

CONCLUSION

- Immediately screen all COVID-19–positive patients for possible mAb infusions. The infusion is most beneficial early in the infection.
- Be familiar with the screening guidelines and educate your coworkers on the importance and the use of mAbs.
- Be an advocate for your patients and be persistent.
- Assess for the possibility of home infusions.

Thank you

Slides, including explanations to the pre-/posttest questions, can be found in the PDF resource associated with this activity.

Q&A


PRE/POSTTEST QUESTIONS

A 52-year-old man with a past medical history of seasonal allergies presents in an Emergency Department with 5 days of fever, a nonproductive cough, and loss of taste and smell. 2 days ago, he started developing shortness of breath and rib pain associated with the coughing that led him to seek evaluation. Pertinent findings on exam were obesity (BMI=35), BP 145/104, RR 28, and bilateral inspiratory rales. His O_2 saturation was 88% of room air that improved to 94% on 2 L NC.

What is a known risk factor for developing severe COVID-19 illness?

A. Rib pain
B. BMI ≥30 (changed to 25)
C. Seasonal allergies
D. Chronic cough

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Many risk factors have been identified that increase the risk of developing severe disease in COVID-19, including advanced age, obesity, and cardiovascular disease (see the CDC website for a comprehensive list). Seasonal allergies, rib pain, and chronic cough have not been identified as a risk for developing severe illness from COVID-19 infection.

1. Centers for Disease Control and Prevention. People with Certain Medical Conditions. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html#diabetes. Accessed February 2, 2021. 2. Williamson EJ, Walker AJ, Bhaskara, K, et al. Factors associated with COVID-19-related death using OpenSAFELY. *Nature*. 2020; 584(7821):430-436.

OUTCOME QUESTION

Cindy is a 68-year-old female who received her first dose of her COVID-19 mRNA vaccine 1 week ago. She reports to the clinic today with fatigue, dry cough, and a fever. She tests positive for SARS-CoV-2.

Which of the following reflects treatment options for Cindy?

A. Cindy may receive bamlanivimab but must restart the vaccination series 3 months after the infusion

B. Cindy may receive casirivimab/imdevimab but must delay her second dose of vaccination for 3 months after infusion

C. Cindy may receive bamlanivimab/etesevimab and receive her second COVID-19 mRNA vaccine on schedule

D. Cindy may not receive a neutralizing mAb because she is already partially vaccinated

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- There are no data on the efficacy or safety of administering COVID-19 vaccines to patients who received neutralizing mAbs. All recommendations from the CDC and other sources are based on the pharmacokinetic properties of the medications (including half-life) and reinfection data.
  - It is recommended that reinfection with SARS-CoV-2 is unlikely within 3 months after initial infection; vaccination should be delayed for 90 days to avoid any potential interaction from the neutralizing mAb on vaccine-induced immunity

This recommendation is for all patients who have not received any vaccine dose and those who received the first dose of the mRNA vaccine.

- It is not recommended to restart the vaccine series if the second dose has to be delayed

Vaccination does not affect any treatment decisions, including the ability to select neutralizing mAbs for patients who are diagnosed with COVID-19 after vaccination.

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fpfizer%2Fclinical-considerations.html. Accessed March 14, 2021.

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- Based on the available data, the FDA approved emergency use of neutralizing mAbs for the treatment of mild to moderate COVID-19.

  Providers are required to review the Healthcare Provider Emergency Use Authorization; provide information in the Fact Sheet for Patients, Parents, and Caregivers with the patient or patient's representative; and instruct the patient to continue to self-isolate and use infection control measures according to the CDC.

1. https://www.fda.gov/media/143603/download. Accessed March 25, 2021. 2. https://www.fda.gov/media/143892/download. Accessed March 25, 2021. 3. https://www.fda.gov/media/145802/download. Accessed March 25, 2021.