



Clinical Trials and EUA Update

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Agenda

- Original EUA trials/data
- Recent clinical trial updates
- EUA updates

Current Emergency Use Authorizations (EUAs)

Drug	Bamlanivimab (Lilly)	Casirivimab/Indevimab (Regeneron)
Trial	BLAZE-1 ¹ (Ph2 interim results) Arms (1:1:1:1) N=452 • Bam 700 mg, Bam 2800 mg, Bam 7000 mg, placebo	2067 ² (Phase 1-3 interim results) Arms (1:1:1) N=799 • REGEN-COV 2.4g, REGEN-COV 8g, placebo
Primary Endpoint	D11 change in log viral load 2800mg arm: -0.53 versus placebo (p=0.02)	D7 change in log viral load Pooled treatment group=-0.36 (p<0.0001)
Secondary Endpoint	Hospitalizations/ER visits High risk patients (pooled)= ~70% decrease 4% (4/95) vs. 15% (7/48) placebo	Medically attended visits High risk patients (pooled)= ~70% decrease 3% (4/151) vs. 9% (7/78) placebo
Status	EUA (November 9, 2020): Bam 700 mg high risk outpatients based on potential to decrease hospitalizations	EUA (November 21, 2020): REGEN-COV 2.4g high risk outpatients based on potential to decrease hospitalizations

1. <https://www.nejm.org/doi/full/10.1056/NEJMoa2029849>

2. <https://www.fda.gov/media/144468/download>, https://www.nejm.org/doi/full/10.1056/NEJMoa2035002?query=recirc_curatedRelated_article

Recent Data: Bamlanivimab and Etesevimab

Drug	Bamlanivimab / Etesevimab	Bamlanivimab	Bamlanivimab / Etesevimab
Trial	BLAZE-1 ¹ (Ph2 final results) Arms: (1:1:1:1), (1:1) N=577 <ul style="list-style-type: none"> Bam 700 mg, 2800 mg, 7000 mg, placebo Bam 2800mg/ ete 2800mg, placebo 	BLAZE-2 ² (post-exposure prophylaxis in LTCF) Arms: (1:1) N=299 <ul style="list-style-type: none"> Bam 4200mg, placebo 	BLAZE-1 ³ (Ph3) Arms: (1:1) N=1035 <ul style="list-style-type: none"> Bam 2800mg/ete 2800mg, placebo
Primary Endpoint	D11 change in viral load Combo arm: -0.57; p=0.01	Prevention of symptomatic COVID-19 OR=0.2; p=0.00026 80% reduction for residents	Hospitalizations/death D29 70% reduction vs. placebo 2.1% (11/517) vs. 7% (36/518); p=0.0004 Death: 10/518 placebo, 0/517 bam/ete
Secondary Endpoint	Hospitalizations/ER visits High risk patients ~70% decrease Pooled mono= 4% (4/101), Combo= 0% (0/31) placebo= 13.5% (7/52)		Viral load and symptom decrease all significant
Status	EUA under review	EUA to be submitted	Press release

1. <https://investor.lilly.com/news-releases/news-release-details/lillys-neutralizing-antibody-bamlanivimab-ly-cov555-prevented>
2. <https://investor.lilly.com/news-releases/news-release-details/new-data-show-treatment-lillys-neutralizing-antibodies>
3. <https://jamanetwork.com/journals/jama/fullarticle/2775647>

Recent Data: Casirivimab and Imdevimab

Drug	Casirivimab / Imdevimab
Trial	Phase 3 prevention ¹ (interim) Arms: (1:1) N=400 <ul style="list-style-type: none">• REGEN-COV 2.4g SQ• placebo
Primary Endpoint	Symptomatic infection 8/223 placebo vs. 0/186 REGEN-COV Symptomatic and asymptomatic 23/223 placebo vs. 10/186 REGEN-COV.
Status	Press release

1. <https://investor.regeneron.com/news-releases/news-release-details/regeneron-reports-positive-interim-data-regen-covtm-antibody>

EUA Updates Bamlanivimab¹

- **Shortened infusion times (Section 2.4)**

Drug: Add 20 mL of bamlanivimab (1 vial) to a prefilled infusion bag and administer as instructed below		
Size of prefilled 0.9% Sodium Chloride infusion bag	Maximum Infusion Rate	Minimum Infusion Time
50 mL	270 mL/hr	16 minutes
100 mL	270 mL/hr	27 minutes
150 mL	270 mL/hr	38 minutes
250 mL	270 mL/hr	60 minutes

- **Addition of new symptoms to Hypersensitivity and infusion-related reaction Warning and Precaution (Section 5.1)**
- **Addition of Warning and Precaution for clinical worsening after bamlanivimab administration (Section 5.2)**

1. <https://www.fda.gov/media/143603/download>

Combatcovid.hhs.gov

combatCOVID.hhs.gov

HOME I'VE NEVER HAD COVID-19 I HAVE COVID-19 NOW I HAD COVID-19 IN THE PAST I'M A HEALTHCARE PROVIDER

JOIN THE FIGHT

Find ways to prevent, treat or help fight COVID-19.

YOU CAN COMBAT COVID-19

Scientists and healthcare providers still need your help to develop safe and effective vaccines and medicines to prevent and treat COVID-19. Scientists and healthcare providers continue to develop new vaccines and test treatments for COVID-19.

If you've never had COVID-19, you can join a clinical trial for these vaccines or for other ways to prevent the disease.

If you have COVID-19 now, learn what your treatment options are or how to join a clinical trial.

If you have had COVID-19 in the past, you can donate plasma or blood to help others recover.

Healthcare Providers: Learn more about COVID-19 therapeutic options and ongoing clinical trials.

JOIN A VACCINE CLINICAL TRIAL

LEARN ABOUT TREATMENT OPTIONS

JOIN A TREATMENT CLINICAL TRIAL

DONATE PLASMA TO HELP OTHERS

VIEW THE HEALTHCARE PROVIDER'S GUIDE

AVAILABLE COVID-19 TREATMENT OPTIONS

If you or a loved one test positive for COVID-19, you may now have treatment options. COVID-19 treatment options are available for patients with mild to moderate symptoms and for hospitalized patients. Mild symptoms may include fever, cough, sore throat, malaise (feeling unwell), headache, muscle pain, nausea, vomiting, diarrhea, and loss of taste and smell. Moderate symptoms may also include shortness of breath.

The U.S. Food and Drug Administration (FDA) has authorized treatments for emergency use. Talk to your healthcare provider about treatment options. Your provider will know the best option for you, based on your symptoms and your health history.

TREATMENT FOR NON-HOSPITALIZED COVID-19-POSITIVE PATIENTS

Monoclonal antibodies attack the virus

SYMPTOMS Mild to moderate

REQUIREMENTS Healthcare provider's referral, receiving treatment within 10 days of having the first symptoms of COVID-19, 12 years of age or older, high risk status* including obesity, diabetes, chronic kidney disease, weakened immune system, or taking a medicine that weakens the immune system.

*Click [here](#) to learn more about high risk status.

OUT-OF-HOSPITAL TREATMENT OPTIONS FOR PATIENTS WITH MILD TO MODERATE COVID-19 ILLNESS

The following treatments have been authorized for emergency use by the FDA for non-hospitalized patients with mild to moderate cases of COVID-19. The FDA has determined that the known and potential benefits of these treatments for non-hospitalized patients are greater than the treatments' known and potential risks.

Monoclonal antibody treatments: The FDA has issued emergency use authorization for two investigational monoclonal antibody treatments that can attach to SARS-CoV-2, the coronavirus that causes COVID-19. These antibodies could help the immune system recognize and respond more effectively to the virus.

These treatments have been authorized for patients with mild to moderate cases: those who have had symptoms for 10 days or less, who are 12 years of age and older, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. This includes people who are 65 years old or older, and who have certain chronic medical conditions. Learn more about antibody treatments with [bamlanivimab](#), [casirivimab](#) and [imdevimab](#).

Learn what monoclonal antibodies are and how they can help.

<http://combatCOVID.hhs.gov>



Thank you!