Monoclonal Antibodies for COVID-19: The Clinical Evidence

Monoclonal antibodies are laboratory-produced proteins that act as substitute antibodies to restore, enhance, or mimic the immune system's attack on cells. Given the novel nature of SARS-CoV-2, the virus that causes COVID-19, the science is evolving rapidly. This fact sheet provides the latest clinical evidence available.

CLINICAL TRIALS AND FDA EMERGENCY USE AUTHORIZATIONS (EUA)

As of March 29, 2021, the following monoclonal antibodies have been authorized by the FDA for emergency use:

- **REGEN-COV (casirivimab and imdevimab)[1]**
- **Bamlanivimab and etesevimab[2]**

The NIH COVID-19 Treatment Guidelines Panel recommends (AIIa) using one of these combination anti-SARS-CoV-2 monoclonal antibodies to treat outpatients with mild to moderate COVID-19 who are at high risk of clinical progression, as defined by the Emergency Use Authorization.[3]

Rating of Recommendations:

A = Strong; **B** = Moderate; **C** = Optional

Rating of Evidence:

I = One or more randomized trials without major limitations
IIa = Other randomized trials or subgroup analyses of randomized trials
IIb = Nonrandomized trials or observational cohort studies
III = Expert opinion

REGEN-COV (Casirivimab and Imdevimab)[1]:

Reduced Viral Loads, ER Visits, and Hospitalizations

"The **largest reductions in viral load** relative to **placebo occurred in patients with high viral load** (-0.78 log10 copies/mL) or who were seronegative (-0.69 log10 copies/mL) at baseline. Reductions occurring from Day 1 through Day 11 were similar to those for Day 1 through Day 7."[4]

— FDA EUA CDER Scientific Review Document (November 21, 2020): Phase 1 and 2 data from an ongoing trial R10933-10987-COV-2067; data from 799 symptomatic patients.

"When considering only individuals at high risk for progression to severe disease, [...] **hospitalization or emergency room visits were reported in 9% of participants in the placebo group compared to 3% in the combined casirivimab and imdevimab dose groups**"[4] – a 70% relative reduction.

— FDA EUA CDER Scientific Review Document (November 21, 2020): Phase 1 and 2 data from an ongoing trial R10933-10987-COV-2067; data from 799 symptomatic patients.

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Bamlanivimab and Etesevimab[2]:

Reduced ER Visits, Hospitalizations, and Deaths

"[...] **COVID-19 related hospitalization or death [...] occurred in 36 subjects treated with placebo (7%) as compared to 11 events in subjects treated with bamlanivimab 2,800 mg and etesevimab 2,800 mg together (2%)**, a 70% [relative] reduction. **There were 10 deaths in subjects treated with placebo and no deaths in subjects treated with bamlanivimab 2,800 mg and etesevimab 2,800 mg together**."[5]

— FDA EUA CDER Scientific Review Document (February 9, 2021): Phase 3 data from BLAZE-1 trial; total of 1035 participants at high risk for progression to severe COVID-19 disease were enrolled in Treatment Arms 7-8 (efficacy results).

For more information, visit

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English: 1-877-332-6585 • Spanish: 1-877-366-0310

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References

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3. Statement on Anti-SARS-CoV-2 Monoclonal Antibodies EUA. (2021, April 8). COVID-19 Treatment Guidelines. https://www.covid19treatmentguidelines.nih.gov/statement-on-anti-sars-cov-2-monoclonal-antibodies-eua/
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