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 information sheet provides the latest clinical evidence available.

CLINICAL TRIALS AND FDA EMERGENCY USE AUTHORIZATIONS (EUA)

The following monoclonal antibody products have been authorized by the FDA for emergency use. The first two are available at no cost to patients:

- **REGEN-COV™ (casirivimab and imdevimab)[1]**
- **Bamlanivimab and etesevimab[2]**
- **Sotrovimab[3]**

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.[4]

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 Hospitalization and Death

"COVID-19-related hospitalization or all-cause death through Day 29 [...], events occurred in 7 (1.0%) subjects treated with 600 mg of casirivimab and 600 mg of imdevimab compared to 24 (3%) subjects concurrently randomized to placebo, demonstrating **a 70% reduction in COVID-19-related hospitalization or all-cause death compared to placebo** (p=0.0024)."[5]

— FDA-authorized Fact Sheet for Healthcare Providers (June 3, 2021): Phase 3 data from an ongoing COV-2067 trial; data from 4,567 randomized subjects.

Subcutaneous Injection

"[The] safety findings with subcutaneous administration in the casirivimab and imdevimab arm were similar to the safety findings observed with intravenous administration in COV-2067."[5]

— FDA-authorized Fact Sheet for Healthcare Providers (June 3, 2021): Analysis from HV-2093 trial; data from 969 randomized healthy volunteer adult subjects.

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Bamlanivimab and Etesevimab[2]:

Reduced Viral Load, Hospitalization, and Death

"[...] COVID-19 related hospitalization [...] or death [...] occurred in 15 subjects treated with placebo (6%) **as compared to 4 events in subjects treated with bamlanivimab** 700 mg **and etesevimab** 1,400 mg **together** (0.8%)**, an 87%** [relative] **reduction. There were 4 deaths in subjects treated with placebo and no deaths in subjects treated with bamlanivimab** 700 mg **and etesevimab** 1,400 mg **together [...]."**[6]

"The median time to **sustained symptom resolution [...] was 8 days for subjects treated with bamlanivimab** 700 mg **and etesevimab** 1,400 mg **together as compared with 10 days for subjects treated with placebo** [...]."[6]

— *FDA-authorized Fact Sheet for Healthcare Providers (May 14, 2021): Phase 3 data from an ongoing BLAZE-1 (bamlanivimab 700 mg and etesevimab 1,400 mg) trial; Bamlanivimab and etesevimab at the authorized doses of 700 mg and 1,400 mg have been administered together to approximately 800 subjects in clinical trials to participants at high risk for progression to severe COVID-19 disease.*

Sotrovimab[3]:

Reduced Progression of COVID-19 at Day 29

"[P]rogression of COVID-19 at Day 29, was reduced by 85% (adjusted relative risk reduction) in recipients of sotrovimab versus placebo (p = 0.002)."[7]

— *FDA-authorized Fact Sheet for Healthcare Providers (May 26, 2021): Phase 1/2/3 data from an ongoing Phase 1/2/3 COMET-ICE trial; data from 583 randomized subjects.*

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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6. Fact Sheet for Healthcare Providers Emergency Use Authorization (EUA) of bamlanivimab and etesevimab. (revised May 14, 2021). https://www.fda.gov/media/145802/download
7. Fact Sheet for Healthcare Providers Emergency Use Authorization (EUA) of sotrovimab. (May 26, 2021). https://www.fda.gov/media/149534/download