
# CLINICAL STUDIES OF NEUTRALIZING ANTIBODIES (NABs)

## IN THE OUTPATIENT COVID-19 SETTING

Until November 2020, the only FDA-authorized therapies for COVID-19 were for hospitalized patients. Since then, two therapies, bamlanivimab and casirivimab/imdevimab (all nAbs), received emergency use authorization for the treatment of high-risk patients in the outpatient setting. The authorizations were based on trials that demonstrated reduced viral load and hospitalization/emergency department (ED) use in patients receiving the therapies. A third nAb for use in the outpatient setting, VIR-7831, is in late-stage clinical trials. This table provides highlights of the trials of the three therapies; in all trials, therapy was administered through IV infusion.

### BAMLANIVIMAB[1,2]

#### STUDY DESIGN

- Phase 2 (BLAZE-1)
- Randomized 452 patients with mild-to-moderate COVID-19 symptoms and positive test to 700 mg, 2800 mg, or 8000 mg dose of study drug or to placebo

#### PRIMARY ENDPOINT

Change in viral load from baseline to day 11 vs placebo

#### RESULTS

- 2800 mg dose met primary endpoint vs placebo (-0.53, 95% CI; -0.98 to -0.08; *P*=0.02)
- Viral load lower by a factor of 3.4
- Improvement occurred by day 3 postinfusion
- 1.6% of patients on BAM were hospitalized or visited ED vs 6.3% on placebo

#### ADVERSE EVENTS

- Infusion reactions (2.3% BAM vs 1.4% placebo)
- No SAEs

### CASIRIVIMAB/IMDEVIMAB[3]

#### STUDY DESIGN

- Phase 1/2
- Randomized 799 nonhospitalized adults with mild-to-moderate COVID-19 symptoms to single IV infusion of 2400 mg CAS/IMD (1200 mg of each); 8000 mg CAS/IMD (4000 mg each), or placebo

#### PRIMARY ENDPOINT

Viral load at day 7 vs placebo

#### RESULTS

- Significantly* lower viral load in intervention group vs placebo at day 7
- Average of 3% of intervention group hospitalized or visited ED vs 9% in placebo
- No difference in outcomes based on dose

#### ADVERSE EVENTS

- Moderate-to-severe infusion and hypersensitivity reactions
- No SAEs

### VIR-7831[4,5]

#### STUDY DESIGN

- Phase 2/3
- Phase 2: All patients receive VIR-7831
- Phase 3: Patients randomized to study drug or placebo
- Estimated enrollment: 1360 COVID-19–positive outpatients

#### PRIMARY ENDPOINT

Proportion of participants who progress (hospitalization >24 hours or death at day 8, day 15, or day 22) through day 29

#### RESULTS

- Estimated primary completion date: January 2021
- Estimated study completion date: July 2021

#### ADVERSE EVENTS

N/A

*No specific number, *P*-value, or CI provided.

BAM=bamlanivimab. CAS/IMD=casirivimab/imdevimab. CI=confidence interval. IV=intravenous. SAE=severe adverse event.

Last updated on January 5, 2021.

# REFERENCES


1. Chen P, Nirula A, Heller B, et al. SARS-CoV-2 Neutralizing Antibody LY-CoV555 in Outpatients with Covid-19. *NEJM*. 2020.

2. Food and Drug Administration. Fact Sheet For Health Care Providers Emergency Use Authorization (EUA) Of Bamlanivimab. https://www.fda.gov/media/143603/download. Published December 2020. Accessed January 5, 2021.

3. Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Authorizes Monoclonal Antibodies for Treatment of COVID-19. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19. Published November 21, 2020. Accessed January 5, 2020.

4. Clinicaltrials.gov. VIR-7831 for the Early Treatment of COVID-19 in Outpatients (COMET-ICE). https://clinicaltrials.gov/ct2/show/NCT04545060. Published 2021. Accessed January 5, 2021.

5. Clinicaltrials.gov. ACTIV-3: Therapeutics for Inpatients With COVID-19 (TICO). https://clinicaltrials.gov/ct2/show/NCT04501978?term=VIR-7831&cond=COVID-19&draw=2&rank=2. Published 2021. Accessed January 5, 2021.


forefront COLLABORATIVE