Table 3a. Anti-SARS-CoV-2 Monoclonal Antibodies: Selected Clinical Data

Last Updated: December 16, 2021

This table describes only clinical trials that have evaluated anti-SARS-CoV-2 mAbs for the treatment of COVID-19. Please refer to the Prevention of SARS-CoV-2 Infection section for a discussion of clinical trials that have evaluated anti-SARS-CoV-2 mAbs for PEP of SARS-CoV-2 infection.

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| **BLAZE-1**: Double-Blind, Phase 3 RCT of Bamlanivimab 700 mg Plus Etesevimab 1,400 mg in Nonhospitalized Patients With Mild to Moderate COVID-19¹ | **Participant Characteristics:**  
- Median age 56 years; 30% ≥65 years; 53% women  
- 87% White, 27% Hispanic/Latinx, 8% Black/African American  
- Mean duration of symptoms was 4 days.  
- 76% had mild COVID-19 and 24% had moderate COVID-19.  
**Primary Outcomes:**  
- COVID-19-related hospitalizations or all-cause deaths by Day 29: 4 (0.8%) in BAM plus ETE arm vs. 15 (5.8%) in placebo arm (Δ [95% CI] = -5.0 [-8.0, -2.1]; 𝑃 <0.001).  
- All-cause deaths by Day 29: 0 in BAM plus ETE arm vs. 4 (1.6%) in placebo arm.  
**Interpretation:**  
- Compared to placebo, BAM plus ETE was associated with 5% absolute reduction and 87% relative reduction in COVID-19-related hospitalizations or all-cause deaths. |  |
| **BLAZE-1**: Double-Blind, Phase 3 RCT of Bamlanivimab 2,800 mg Plus Etesevimab 2,800 mg in Nonhospitalized Patients With Mild to Moderate COVID-19² | **Participant Characteristics:**  
- Mean age 53.8 years; 31% ≥65 years; 52% women; 48% men  
- 87% White, 29% Hispanic/Latinx, 8% Black/African American  
- Median days from symptom onset to infusion was 4 days.  
- 77% had mild COVID-19.  
**Primary Outcomes:**  
- COVID-19-related hospitalizations or all-cause deaths by Day 29: 11 (2.1%) in BAM plus ETE arm vs. 36 (7.0%) in placebo arm; relative risk difference: 70% (𝑃<0.001).  
- All-cause deaths by Day 29: 0 in BAM plus ETE arm vs. 10 (1.9%) in placebo arm.  
**Interpretation:**  
- Compared to placebo, BAM plus ETE was associated with 4.8% absolute reduction and 70% relative reduction in COVID-19-related hospitalizations or all-cause deaths. |  |
### Methods

#### BLAZE-1: Double-Blind, Phase 3 RCT of Bamlanivimab 2,800 mg Plus Etesevimab 2,800 mg in Nonhospitalized Patients With Mild to Moderate COVID-19<sup>2</sup>, continued

**Primary Endpoint:**
- COVID-19-related hospitalization or death from any cause by Day 29

**Secondary Endpoint:**
- SARS-CoV-2 VL >5.27 log<sub>10</sub> copies/mL at Day 7

#### Results

**Secondary Outcome:**
- Percentage of patients with SARS-CoV-2 VL >5.27 log<sub>10</sub> copies/mL at Day 7: 9.8% in BAM plus ETE arm vs. 29.5% in placebo arm (P < 0.001).

### Interpretation

Compared to placebo, CAS 600 mg plus IMD 600 mg was associated with 2.2% absolute reduction and 70% relative risk reduction in COVID-19-related hospitalizations or all-cause deaths. Compared to placebo, CAS 1,200 mg plus IMD 1,200 mg was associated with 3.3% absolute reduction and 71% relative risk reduction in COVID-19-related hospitalizations or all-cause deaths.

### Key Inclusion Criteria:

- Aged ≥18 years
- Laboratory-confirmed SARS-CoV-2 infection
- Symptom onset within 7 days of randomization
- For patients included in the modified full analysis only:
  - ≥1 risk factor for severe COVID-19
  - Positive SARS-CoV-2 RT-PCR at baseline

### Interventions:

- Single IV infusion of:
  - CAS 600 mg plus IMD 600 mg (n = 736) or placebo (n = 748)
  - CAS 1,200 mg plus IMD 1,200 mg (n = 1,355) or placebo (n = 1,341)

### Primary Endpoint:

- ≥1 COVID-19-related hospitalization or death from any cause through Day 29

### Participant Characteristics:

- Median age 50 years; 35% Hispanic/Latinx, 5% Black/African American
- Median duration of symptoms prior to enrollment was 3 days.

### Primary Outcomes:

- COVID-19-related hospitalizations or all-cause deaths through Day 29:
  - 7 (1.0%) in CAS 600 mg plus IMD 600 mg arm vs. 24 (3.2%) in placebo arm (P = 0.002).
  - 18 (1.3%) in CAS 1,200 mg plus IMD 1,200 mg arm vs. 62 (4.6%) in placebo arm (P < 0.001).

### All-Cause Deaths:

- 1 (0.1%) in CAS 600 mg plus IMD 600 mg arm vs. 1 (0.1%) in placebo arm.
- 1 (<0.1%) in CAS 1,200 mg plus IMD 1,200 mg arm vs. 3 (0.2%) in placebo arm.
COMET-ICE: Double-Blind, Phase 3 RCT of Sotrovimab in Nonhospitalized Patients With Mild to Moderate COVID-19, Interim Analysis

**Key Inclusion Criteria:**
- Aged ≥18 years with ≥1 comorbidity or aged ≥55 years
- Laboratory-confirmed COVID-19
- Symptom onset ≤5 days before enrollment

**Key Exclusion Criteria:**
- Hospitalized or requiring supplemental oxygen
- Severely immunocompromised

**Interventions:**
- SOT 500 mg IV (n = 291)
- Placebo (n = 292)

**Primary Endpoint:**
- Hospitalization or death from any cause by Day 29

**Participant Characteristics:**
- Median age 53 years; 22% ≥65 years
- 63% Hispanic/Latinx, 7% Black/African American

**Primary Outcome:**
- Hospitalizations or all-cause deaths by Day 29: 3 (1%) in SOT arm vs. 21 (7%) in placebo arm (P = 0.002).

**Interpretation:**
- Compared to placebo, SOT was associated with 6% absolute reduction and 85% relative risk reduction in all-cause hospitalizations or deaths.

**References**


