SUPPLEMENTARY MATERIAL

1. METHODS

Sample size

A sample size of approximately 500 adult patients per treatment arm would provide >90% power to demonstrate if bamlanivimab and etesevimab together is statistically significantly better than placebo (defined as an odds ratio <1 in the proportion of patients experiencing COVID-related hospitalization or any-cause death). Treatment arm 9 of BLAZE-1 (700mg of bamlanivimab and 1400 mg etesevimab together) began enrolment after arm 7 (2800 mg of bamlanivimab and 2800 etesevimab together), therefore additional participants were enrolled in treatment arm 8 (placebo) to ensure at least a 33% increase in placebo participants and adequate placebo control for the primary comparison of treatment arms 8 and 9. Randomization was planned to be 1:2 (treatment arm 8 : treatment arm 9) allocation ratio. It was anticipated that the analyses for treatment arms 8 and 9 would utilize approximately 750 placebo patients in treatment arm 8 versus approximately 500 for treatment arm 9. This sample size justification was based on the primary endpoint which was

informed from available data on hospitalization or death events from the Phase 2 portion (a placebo event rate of 8.7% and a relative reduction of 60% for bamlanivimab and etesevimab). There was no set sample size for the adolescent patients.

Dose justification

The 700 mg level of bamlanivimab was selected based on its confirmation as a saturating dose in the BLAZE-1 interim analysis based on viral load, symptoms, and clinical outcomes[1]. The 1400 mg level of etesevimab was selected as the maximum therapeutic dose based on an approximate 2-fold higher IC50 compared to bamlanivimab. This dose was expected to reduce viral load and have a sustained concentration above the respective IC90 of viral neutralization in 90% of the patient population for at least 28 days.

Inclusion Criteria

Participants are eligible to be included in the study if all the following criteria apply:

Age

- Are ≥12 years of age at the time of screening

Disease Characteristics

- Are currently not hospitalized
- Have ≥ 1 mild or moderate COVID-19 symptoms, per the FDA resource page[2]:
    i. Fever
    ii. Cough
    iii. Sore throat
    iv. Malaise
    v. Headache
    vi. Muscle pain
    vii. Gastrointestinal symptoms, or
    viii. Shortness of breath with exertion
- Have sample collection for first positive SARS-CoV-2 viral infection determination ≤3 days prior to start of the infusion

Sex

- Are males or non-pregnant females, and any contraceptives used are consistent with local regulations for those participating in clinical studies

Study Procedures

- Understand and agree to comply with planned study procedures

- Agree to the collection of nasopharyngeal swabs and venous blood

Informed Consent

- The participant or legally authorized representative give signed informed consent and/or assent

Are ≥18 years of age and satisfy at least one of the following at the time of screening

- Are ≥ 65 years of age
- Have a BMI ≥ 35 (BMI is rounded to the nearest whole number, for example, 34.5 is rounded to 35)
- Have chronic kidney disease
- Have type 1 or type 2 diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment, or
- Are ≥ 55 years of age and have
    - cardiovascular disease, or
    - hypertension, or
    - chronic obstructive pulmonary disease or other chronic respiratory disease

Are 12-17 years of age (inclusive) and satisfy at least one of the following at the time of screening

- Have a BMI ≥85th percentile for their age and gender based on CDC growth charts[3]
- Have sickle cell disease
- Have congenital or acquired heart disease
- Have neurodevelopmental disorders, for example, cerebral palsy
- Have a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)
- Have asthma or reactive airway or other chronic respiratory disease that requires daily medication for control
- Have type 1 or type 2 diabetes
- Have chronic kidney disease
- Have immunosuppressive disease, or
- Are currently receiving immunosuppressive treatment

Exclusion Criteria

Participants are excluded from the study if any of the following criteria apply:

Medical Conditions

- Have $SpO2 \leq 93\%$ on room air at sea level or $PaO2/FiO2 < 300$, respiratory rate ≥30 per minute, heart rate ≥125 per minute
- Require mechanical ventilation or anticipated impending need for mechanical ventilation
- Have known allergies to any of the components used in the formulation of the interventions
- Have hemodynamic instability requiring use of pressors within 24 hours of randomization
- Suspected or proven serious, active bacterial, fungal, viral, or other infection (besides

COVID-19) that in the opinion of the investigator could constitute a risk when taking intervention
- Have any co-morbidity requiring surgery within <7 days, or that is considered life threatening within 29 days
- Have any serious concomitant systemic disease, condition or disorder that, in the opinion of the investigator, should preclude participation in this study

Other Exclusions

- Have a history of a positive SARS-CoV-2 serology test
- Have a history of a positive SARS-CoV-2 test prior to the one serving as eligibility for this study
- Have received an investigational intervention for SARS-CoV-2 prophylaxis within 30 days before dosing
- Have received treatment with a SARS-CoV-2 specific monoclonal antibody
- Have received convalescent COVID-19 plasma treatment
- Have participated, within the last 30 days, in a clinical study involving an investigational intervention. If the previous investigational intervention has a long half-life, 5 half-lives or 30 days, whichever is longer, should have passed
- Are concurrently enrolled in any other type of medical research judged not to be scientifically or medically compatible with this study
- Are pregnant or breast feeding
- Are investigator site personnel directly affiliated with this study, and
- Have body weight <40 kg

Sustained Symptom Resolution

The key secondary endpoint, sustained symptom resolution, was defined as 2 consecutive assessments with a score of 0 for shortness of breath, feeling feverish, body aches and pains, sore throat, chills, and headache; and a score of 0 or 1 for fatigue or cough.

RT-PCR

Detection of SARS-CoV-2 was determined from nasopharyngeal swab followed by quantitative reverse transcriptase–polymerase chain reaction (RT-PCR). Sample collection, RNA extraction and RT-PCR were carried out as previously described.[4]

For qualitative endpoints including viral clearance and time to viral clearance, SARS-CoV-2 clearance was defined as 2 consecutive negative tests for SARS-CoV-2. The date of viral clearance was the earliest date of the 2 consecutive negative tests.

For quantitative endpoints including the change from baseline and area under the response viral load curve, the viral load was calculated based on the cycle threshold (Ct) values. The following were taken into account when determining the viral load

- Two Ct values were provided on two different genes: N1 and N2. N1 was used as the primary measure and N2 was only used when the Ct value for N1 was not available.
- Ct values ranged between 0 and 45.
- Negative SARS-CoV-2 tests were associated with a Ct value of 45.
- The ($\log_{10}$) viral load was calculated from the Ct value (45-Ct)/$\log_2 10$, or (45-Ct)/3.321928.

PHVL quantification

PHVL quantification was calculated as previous described.[5] In brief, an additional normalization step was taken to reduce pre-analytical variability in the viral load measurements. As previously described, the N1 or N2 (if N1 was not available) Ct value for any positive sample was subtracted by the Ct value for the RNAse P (RP) mRNA target for that sample minus 26.17:

> N1/N2 Ct value for a sample – [(corresponding RP Ct value for that sample) – 26.17)] = Normalized N1/N2 Ct value.

The correction factor of 26.17 is a historical average value of RP Ct for this assay and was used here to normalize N1/N2 "viral load" calculations to RP.

Following this correction, the RP-normalized log "viral load" was then calculated as follows: Log viral load = (45 - Normalized N1/N2 Ct value)/ $\log_2 10$

2. RESULTS

Subgroup analyses of age and BMI

Of the patients that were <65 years of age, a total of 1 hospitalization or any-cause death by Day 29 was recorded in the bamlanivimab and etesevimab treatment group (0.3% [1/353]), compared with 9 events in the placebo group (4.9% [9/183]) (relative risk [95% CI] = 0.06 [0.01, 0.45], p<0.001).

Of the patients that were ≥65 years of age, a total of 3 hospitalizations or any-cause deaths by Day 29 were recorded in the bamlanivimab and etesevimab treatment group (1.9% [3/158]), compared with 6 events in the placebo group (8% [6/75]) (relative risk [95% CI] = 0.24 [0.06, 0.92], p<0.05).

Of the patients with a BMI <34.5, a total of 4 hospitalizations or any-cause deaths by Day 29 were recorded in the bamlanivimab and etesevimab treatment group (1.4% [4/278]), compared to 4 events in the placebo group (3.2% [4/124]) (relative risk [95% CI] = 0.45 [0.11, 1.75], p>0.05).

Of the patients with a BMI ≥34.5, a total of 0 hospitalizations or any-cause deaths by Day 29 were recorded in the bamlanivimab and etesevimab treatment group (0% [0/222]), compared to 11 events in the placebo group (8.6% [11/128]) (relative risk [95% CI] = 0.00 [0.00, 0.00], p<0.001).

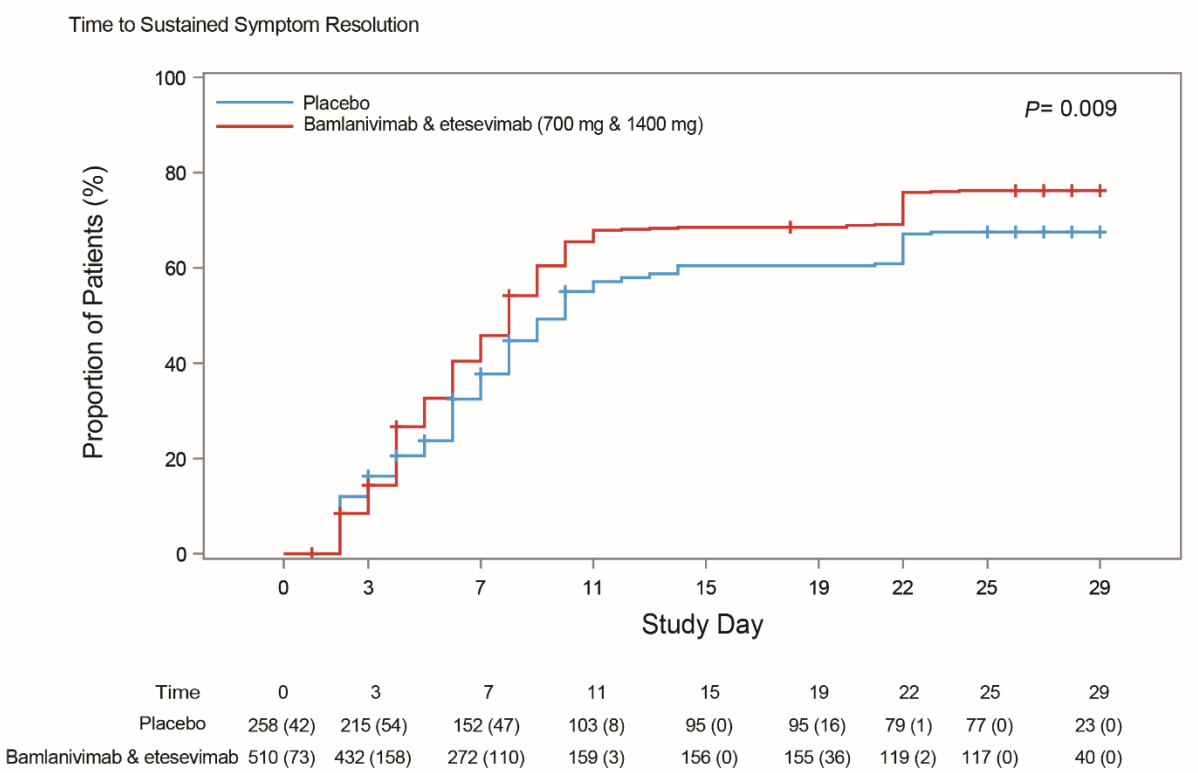

Figure S1 Kaplan-Meier analysis of time to first instance of sustained symptom resolution amongst high-risk patients treated with bamlanivimab & etesevimab versus placebo. Sustained symptom resolution was defined as two consecutive assessments with a score of 0 (absent) for shortness of breath, feeling feverish, body aches and pains, sore throat, chills, and headache; and a score of 0 or 1 (absent or mild) for fatigue or cough, for two consecutive assessments. The number of patients at risk are presented below the graph with the number of events occurring after each timepoint, up to and including the next timepoint, in parenthesis. Patients were infused on Study Day 1.

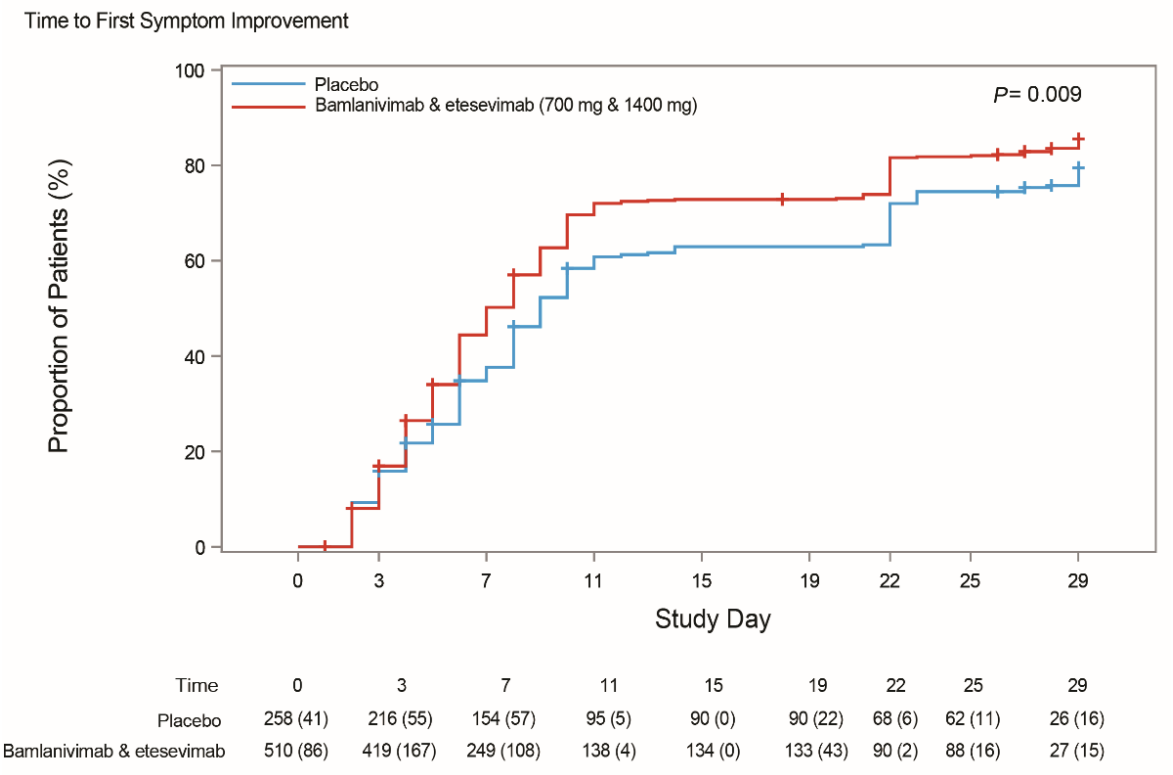

Figure S2 Kaplan-Meier analysis of time to first symptom improvement amongst high-risk patients treated with bamlanivimab & etesevimab versus placebo. Symptom improvement was defined as symptoms on the symptom questionnaire scored as moderate or severe (2 or 3) at baseline are subsequently scored as mild or absent (1 or 0), and symptoms on the symptom questionnaire scored as mild or absent (1 or 0) at baseline are subsequently scored as absent (0). First symptom improvement was defined as the time the patient first satisfies the definition of symptom improvement. The number of patients at risk are presented below the graph with the number of events occurring after each timepoint, up to and including the next timepoint, in parenthesis. Patients were infused on Study Day 1.

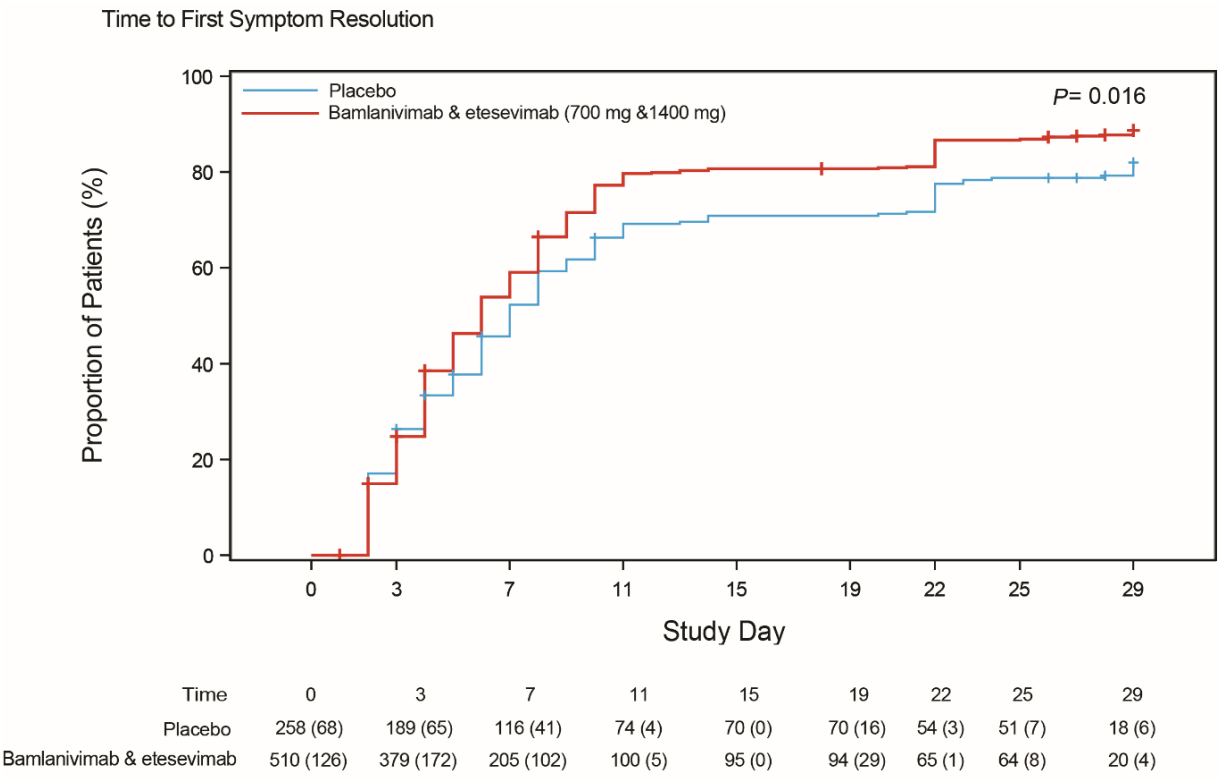

Figure S3 Kaplan-Meier analysis of time to first symptom resolution amongst high-risk patients treated with bamlanivimab & etesevimab versus placebo. Symptom resolution is defined as a score of 0 (absent) for shortness of breath, feeling feverish, body aches and pains, sore throat, chills, and headache; and a score of 0 or 1 (absent or mild) for cough and fatigue on the symptom questionnaire. Time to first symptomatic resolution is the time the patient first satisfies the definition of symptom resolution. The number of patients at risk are presented below the graph with the number of events occurring after each timepoint, up to and including the next timepoint, in parenthesis. Patients were infused on Study Day 1.

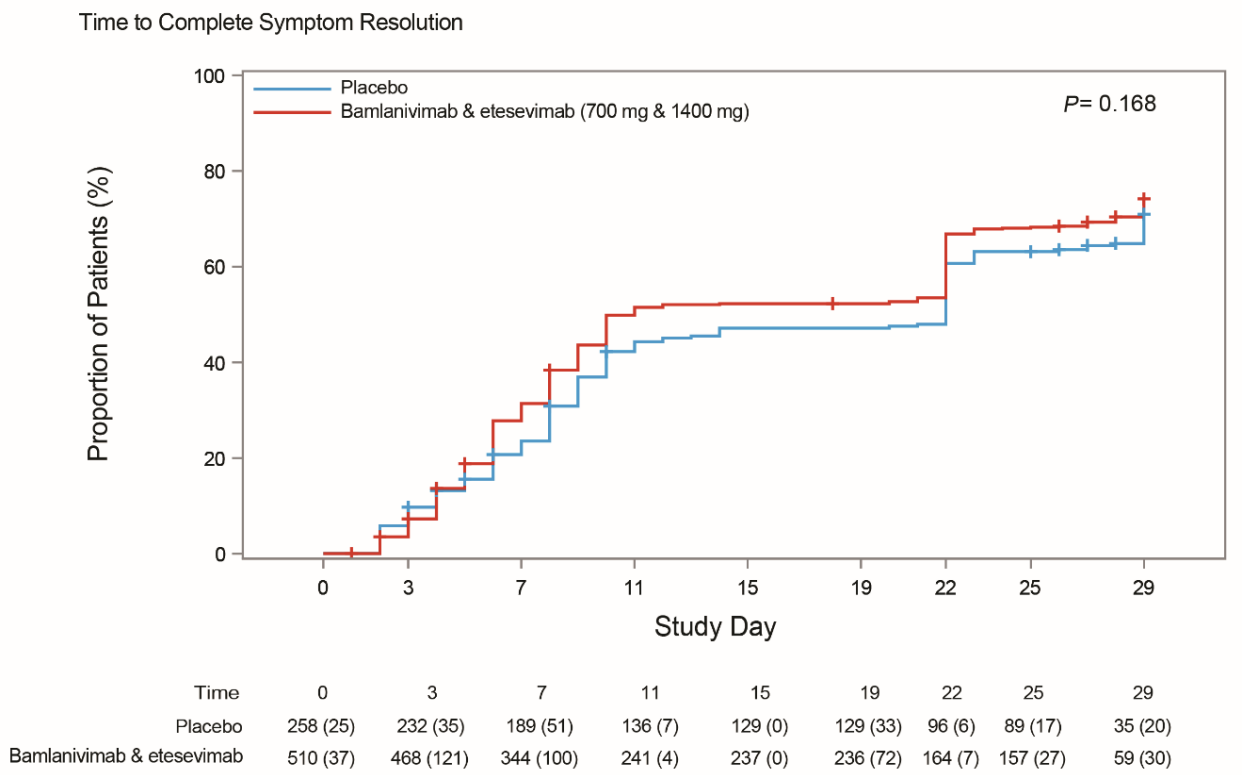

Figure S4 Kaplan-Meier analysis of time to complete symptom resolution amongst high-risk patients treated with bamlanivimab & etesevimab versus placebo. Complete symptom resolution is defined as all symptoms (shortness of breath, feeling feverish, body aches and pains, sore throat, chills, headache, cough, and fatigue) on the symptom questionnaire scored as absent (0). The number of patients at risk are presented below the graph with the number of events occurring after each timepoint, up to and including the next timepoint, in parenthesis. Patients were infused on Study Day 1.

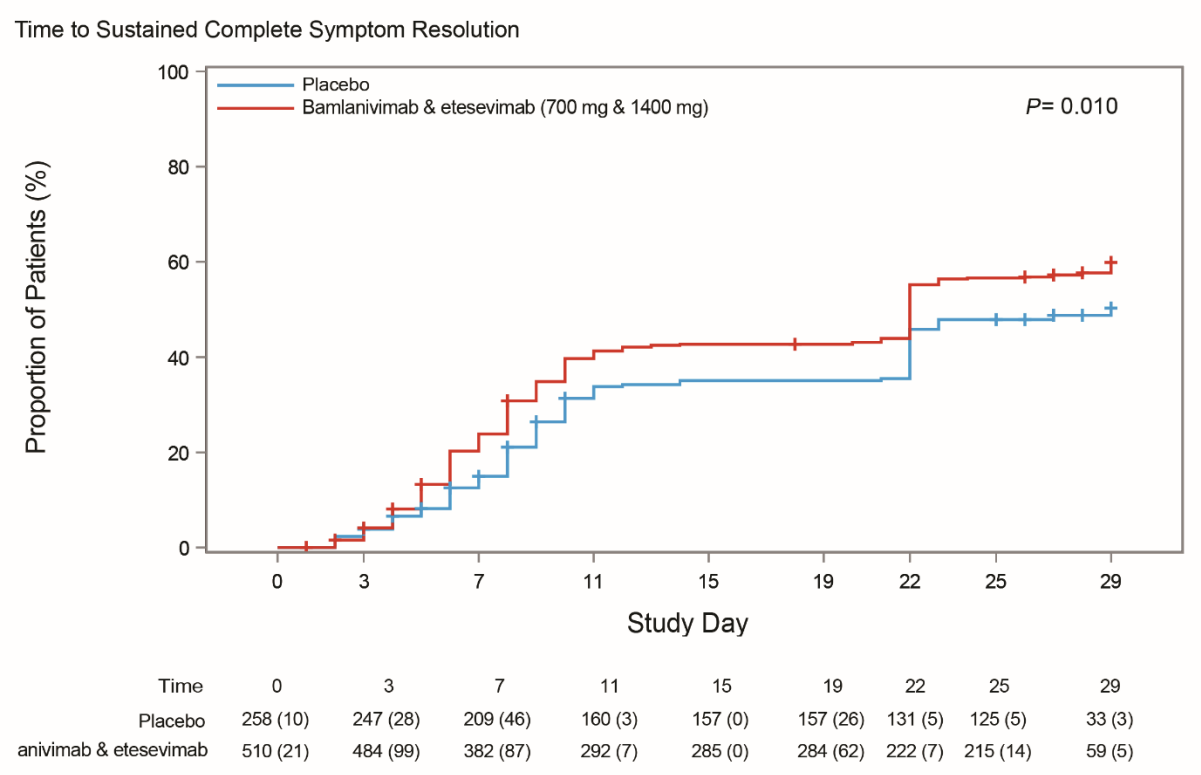

Figure S5 Kaplan-Meier analysis of time to sustained complete symptom resolution amongst high-risk patients treated with bamlanivimab & etesevimab versus placebo. Sustained complete symptom resolution is defined as two consecutive assessments with all symptoms (shortness of breath, feeling feverish, body aches and pains, sore throat, chills, headache, cough, and fatigue) on the symptom questionnaire scored as absent (0). The number of patients at risk are presented below the graph with the number of events occurring after each timepoint, up to and including the next timepoint, in parenthesis. Patients were infused on Study Day 1.

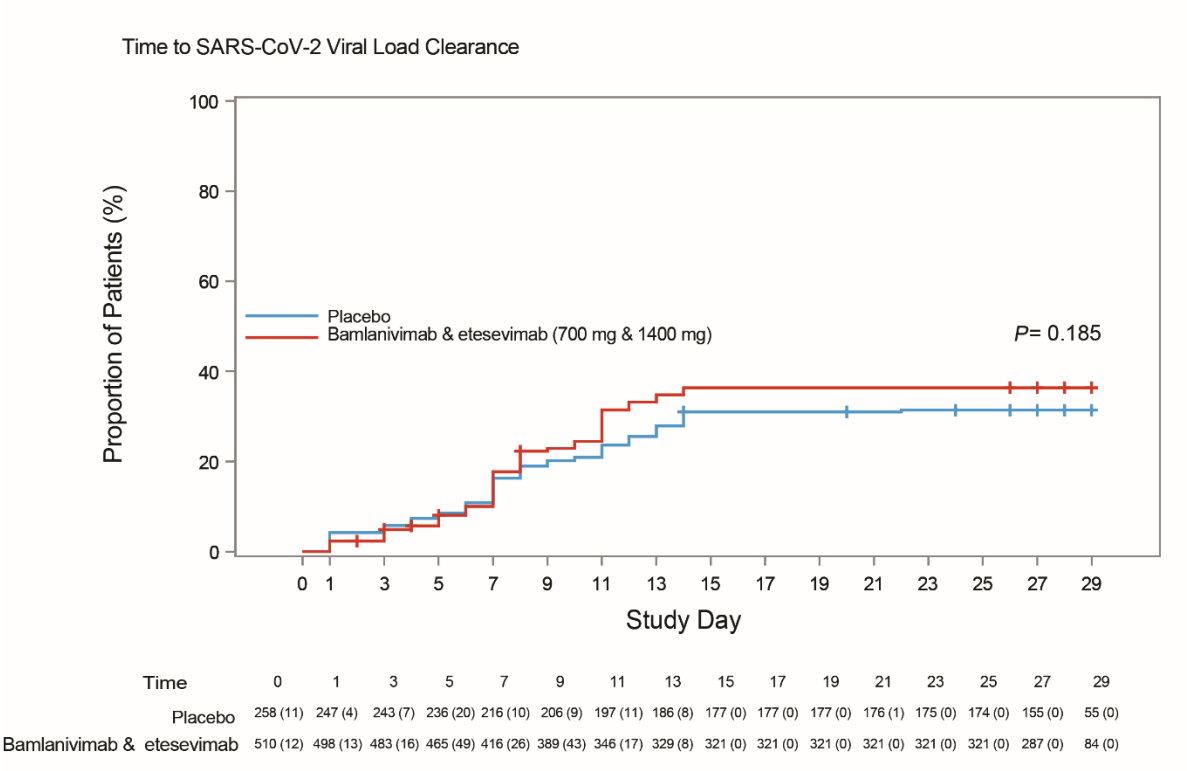

Figure S6 Kaplan-Meier analysis of time to viral clearance amongst high-risk patients treated with bamlanivimab & etesevimab versus placebo. SARS-CoV-2 clearance (yes/no) is defined as two consecutive negative tests for the SARS-CoV-2 virus. The date of viral clearance is defined as the earliest date of the two consecutive negative tests.The number of patients at risk are presented below the graph with the number of events occurring after each timepoint, up to and including the next timepoint, in parenthesis. Patients were infused on Study Day 1.

Table S1. Treatment emergent adverse events present in two or more participants in total

	Placebo (N=258) n (%)	**Bamlanivimab & Etesevimab** (N=511) n (%)	**Total** (N=769) n (%)
TEAEs			
Liver function test increased	3 (1.2)	5 (1.0)	8 (1.0)
C-reactive protein increased	1 (0.4)	3 (0.6)	4 (0.5)
Dizziness	0	4 (0.8)	4 (0.5)
Anemia	0	3 (0.6)	3 (0.4)
Arthralgia	1 (0.4)	2 (0.4)	3 (0.4)
Pruritus	0	3 (0.6)	3 (0.4)
Rash	2 (0.8)	1 (0.2)	3 (0.4)
Urinary tract infection	2 (0.8)	1 (0.2)	3 (0.4)
Anxiety	1 (0.4)	1 (0.2)	2 (0.3)
Asthma	1 (0.4)	1 (0.2)	2 (0.3)
Fall	1 (0.4)	1 (0.2)	2 (0.3)
Gout	1 (0.4)	1 (0.2)	2 (0.3)
Hyperglycemia	0	2 (0.4)	2 (0.3)
Muscle spasms	1 (0.4)	1 (0.2)	2 (0.3)
Nausea	0	2 (0.4)	2 (0.3)
Nephrolithiasis	0	2 (0.4)	2 (0.3)
Neutropenia	0	2 (0.4)	2 (0.3)
Rhinalgia	0	2 (0.4)	2 (0.3)
Vomiting	1 (0.4)	1 (0.2)	2 (0.3)

AE, adverse event; SAE, serious adverse event; TEAE, treatment-emergent adverse event

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Questionnaire obtained by: Lilly	Study ID J2W-MC-PYAB	Subject Number	Visit/Cycle Number	**Signature of Individual Completing Form**
	Investigator Number	Page 1 of 2		**Date Signed by Individual Completing Form**

1. Assessment Date: _____ (DD/MMM/YYYY)

2. Cough
   - ○ Yes
     - ○ Mild
     - ○ Moderate
     - ○ Severe
   - ○ No (Absent)

3. Shortness of breath
   - ○ Yes
     - ○ Mild
     - ○ Moderate
     - ○ Severe
   - ○ No (Absent)

4. Feeling feverish
   - ○ Yes
     - ○ Mild
     - ○ Moderate
     - ○ Severe
   - ○ No (Absent)

5. Fatigue
   - ○ Yes
     - ○ Mild
     - ○ Moderate
     - ○ Severe
   - ○ No (Absent)

6. Body aches and pain
   - ○ Yes
     - ○ Mild
     - ○ Moderate
     - ○ Severe
   - ○ No (Absent)

7. Sore throat
   - ○ Yes
     - ○ Mild
     - ○ Moderate
     - ○ Severe
   - ○ No (Absent)

8. Chills
   - ○ Yes
     - ○ Mild
     - ○ Moderate
     - ○ Severe
   - ○ No (Absent)

9. Loss of appetite
   - ○ Yes
     - ○ Mild
     - ○ Moderate
     - ○ Severe
   - ○ No (Absent)

10. Headache
    - ○ Yes
      - ○ Mild
      - ○ Moderate
      - ○ Severe
    - ○ No (Absent)

11. Loss of taste
    - ○ Yes
    - ○ No

12. Loss of smell
    - ○ Yes
    - ○ No

13. Overall, how bad are your symptoms TODAY (check one)?
    - ○ No symptoms
    - ○ Mild
    - ○ Moderate
    - ○ Severe
    - ○ Very severe

14. Overall, how is your general physical health TODAY (check one)?
    - ○ Poor
    - ○ Fair
    - ○ Good
    - ○ Very good
    - ○ Excellent

15. Have you returned to your usual (pre-COVID) health today (check one)?
    - ○ Yes
    - ○ No