Lilly

SARS-CoV-2 NEUTRALIZING ANTIBODY PROGRAM UPDATE

JANUARY 26, 2021

Agenda

Introduction
Dave Ricks, Chairman and Chief Executive Officer

Neutralizing Antibody Program Update
Dr. Dan Skovronsky, Chief Scientific Officer

Questions & Answers

SAFE HARBOR PROVISION

This presentation contains forward-looking statements that are based on management's current expectations, but actual results may differ materially due to various factors. The company's results may be affected by factors including, but not limited to, the risks and uncertainties in pharmaceutical research and development; competitive developments; regulatory actions; the extent and duration of the effects of the COVID-19 pandemic; litigation and investigations; business development transactions; economic conditions; and changes in laws and regulations, including health care reform.

For additional information about the factors that affect the company's business, please see the company's latest Forms 10-K, 10-Q, and any 8-K filed with the Securities and Exchange Commission.

The company undertakes no duty to update forward-looking statements except as required by applicable law

NEUTRALIZING ANTIBODY PROGRESS

March 12, 2020

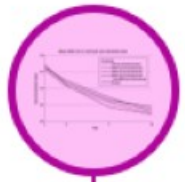
Lilly and AbCellera announce co-development agreement

81 days

June 1, 2020

Lilly announces first patient dosed with bamlanivimab

107 days



September/October 2020

Lilly announces positive proof of concept for bamlanivimab and bamlanivimab + etesevimab in symptomatic COVID-19

54 days

November 9, 2020

US FDA issues Emergency Use Authorization (EUA) for bamlanivimab for treatment of mild-to-moderate COVID-19

EUA request for bamlanivimab + etesevimab submitted

78 days

January 2021

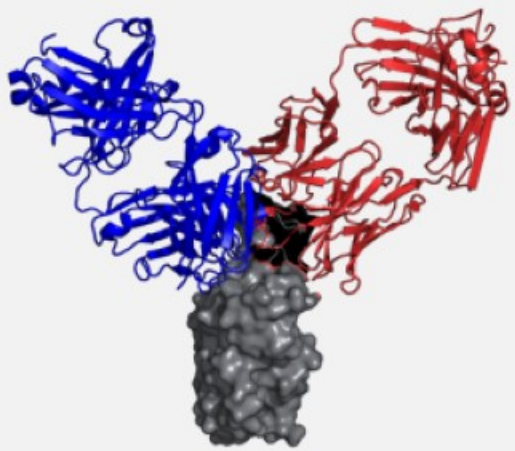
Lilly announces Phase 3 data showing definitive outcomes benefit of SARS-CoV-2 antibodies as both therapy and prophylaxis

LILLY SARS-CoV-2 NEUTRALIZING ANTIBODIES

Combining the two may allow efficacy against a broader range of SARS-CoV-2 variants

BAMLANIVIMAB

- Developed in partnership with AbCellera and NIAID/VRC
- Fully human IgG1; unmodified
- Binds the SARS-CoV-2 Receptor Binding Domain (RBD)



SARS-CoV-2
Receptor Binding Domain

ETESEVIMAB

- Developed in partnership with Junshi Biosciences and IMCAS
- Fully human IgG1; effector null
- Binds a separate site of the RBD

VRC = Vaccine Research Center
NIAID = National Institute of Allergy and Infectious Diseases

IMCAS = Institute of Microbiology, Chinese Academy of Sciences

CLINICAL PROGRAM OVERVIEW

AMBULATORY (RECENTLY DIAGNOSED)

BLAZE-1

- Bamlanivimab alone and together with etesevimab
- 2400+ enrolled

BLAZE-4

- PD-focused study evaluating additional combinations and dose levels
- 700+ enrolled

BLAZE-5

- Real-world study of bamlanivimab in New Mexico
- 3000 subjects planned

ACTIV-2

- Bamlanivimab alone
- Partnership with NIH
- 1200+ enrolled

UNITED

- In-home infusion of bamlanivimab
- Partnership with United Health Group
- 7500 subjects planned

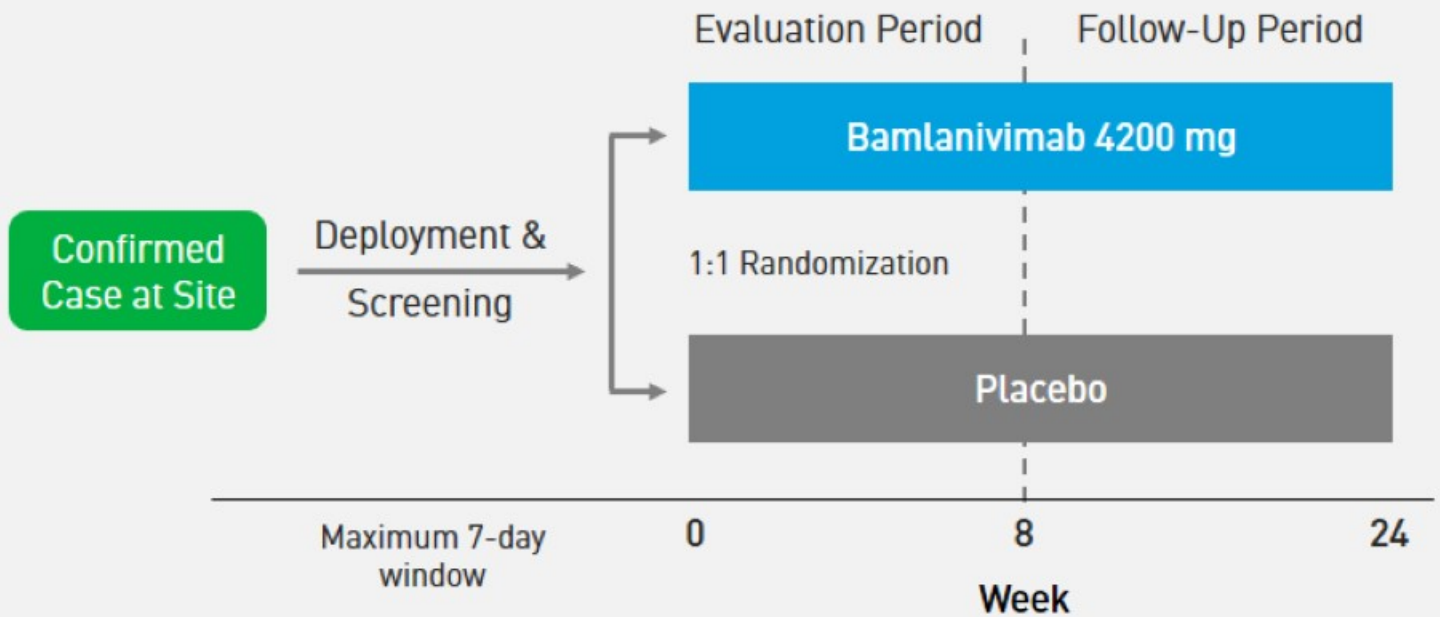
POST-EXPOSURE PROPHYLAXIS

BLAZE-2

- Bamlanivimab alone
- Residents and staff of long-term care facilities
- 1250+ enrolled

BLAZE-2: POST-EXPOSURE PROPHYLAXIS

STUDY DESIGN

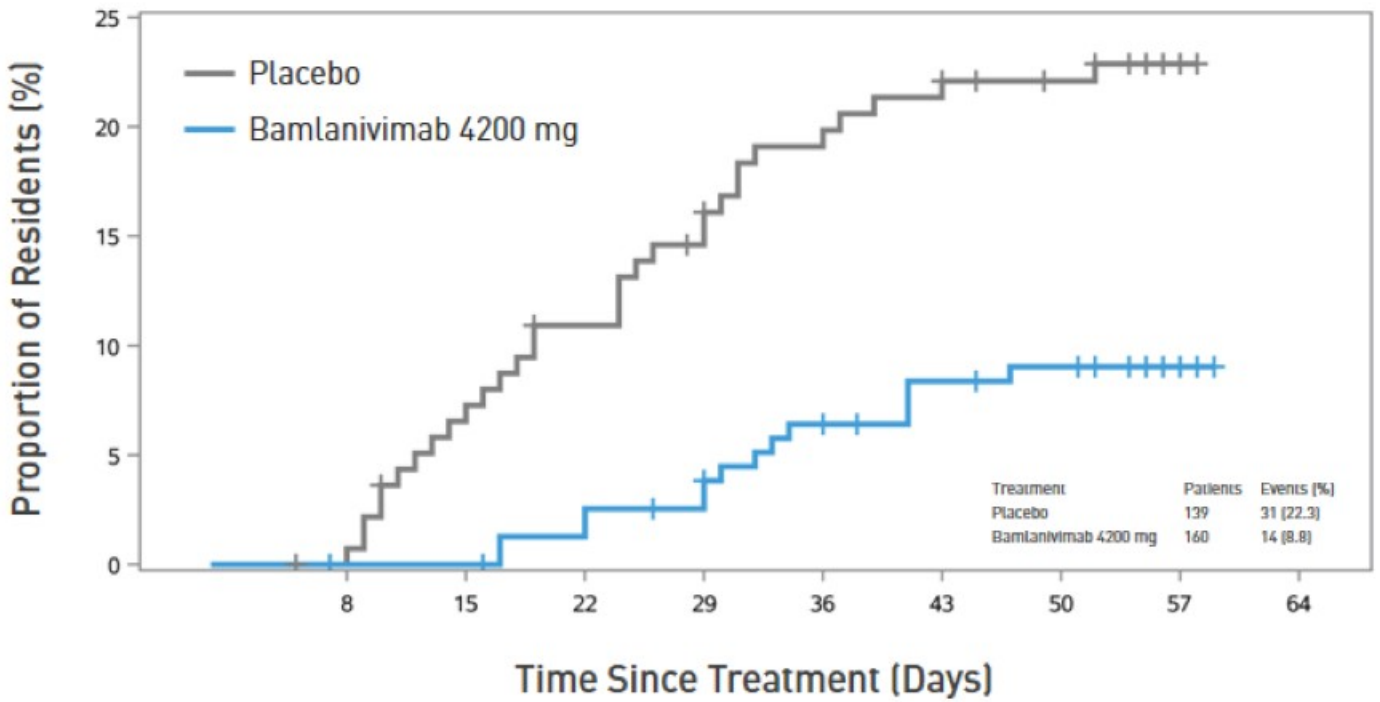


To facilitate rapid prophylaxis and treatment of residents and facility staff, participants were enrolled prior to assessment of baseline SARS-CoV-2 status. This allowed for separate **prevention** and **treatment** analysis populations.

MOBILE RESEARCH UNITS

BLAZE-2: COVID-19 PREVENTION IN RESIDENTS

RESIDENTS WITH SYMPTOMATIC COVID-19 (Prevention Population)



COVID-19 PREVENTION

Odds ratio:	0.20
p-value:	0.00026

Up to 80% reduction in risk

DEATH DUE TO COVID-19

Placebo:	4 of 139 residents
Bamlanivimab:	0 of 160 residents

No deaths due to COVID-19 on bamlanivimab

BLAZE-2: MORTALITY IN TREATMENT POPULATION

DEATH DUE TO ANY CAUSE (RESIDENTS)

	N	Deaths	Rate
Placebo	24	4	17%
Bamlanivimab 4200 mg	17	0	0%

- To facilitate rapid prophylaxis and treatment of residents and facility staff, participants were enrolled prior to assessment of baseline SARS-CoV-2 status
- As a result, a subset of patients was later determined to be SARS-CoV-2 positive at baseline and was analyzed as a separate treatment population (per protocol)

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BLAZE-1: AMBULATORY STUDY DESIGN

PHASE 2 PORTION

Bamlanivimab Monotherapy

- 7000 mg (N = 101)
- 2800 mg (N = 107)
- 700 mg (N = 101)
- Placebo (N = 100)

Bamlanivimab + Etesevimab

- 2800 mg + 2800 mg (N = 109)
- Placebo (N = 56)

Oct 7 Webcast Now Published

N Engl J Med
2021 Jan 21;384(3):229-237

JAMA
2021 Jan; Online ahead of print

Primary Endpoint: Virology
Population: Mild-to-Moderate COVID-19

PHASE 3 PORTION
(Higher Risk Population)

Bamlanivimab + Etesevimab

- 2800 mg + 2800 mg (N = 518)
- Placebo (N = 517)

Presented Today

- 700 mg + 1400 mg (N ~ 500)
- Placebo (N ~ 250)

Fully Enrolled

- Subcutaneous Dose Form
- 700 mg + 1400 mg IV

Planned

Primary Endpoint: Hospitalization or Death Through Day 29
Population: Mild-to-Moderate COVID-19 with Risk Factor(s)

BLAZE-1 PHASE 3: BASELINE CHARACTERISTICS

BASELINE DEMOGRAPHICS AND DISEASE CHARACTERISTICS (SAFETY POPULATION)

	Placebo (N=517)	Bamlanivimab 2800 mg + Etesevimab 2800 mg (N=518)
Female	50%	54%
Hispanic or Latino	30%	29%
Black or African American	8%	9%
Age (median)	56	57
Age ≥ 65	30%	32%
BMI (mean)	33	34
Mild COVID-19	78%	77%
Moderate COVID-19	22%	23%
Duration of symptoms (days, mean)	4.2	4.1
Viral load (mean, CT value, efficacy population)	24.0	24.0

BLAZE-1 PHASE 3: SAFETY AND TOLERABILITY

SUMMARY OF ADVERSE EVENTS

N (%)	Placebo (N=517)	Bamlanivimab 2800 mg + Etesevimab 2800 mg (N=518)
TEAEs	60 (11.6)	69 (13.3)
TEAEs by severity		
Mild	35 (6.8)	37 (7.1)
Moderate	20 (3.9)	24 (4.6)
Severe	5 (1.0)	7 (1.4)
Deaths	2 (0.4)	0
SAEs	5 (1.0)	7 (1.4)

SAE = Serious Adverse Event; TEAE = Treatment-Emergent Adverse Event

- Study-specific clinical events related to COVID-19 including deaths are reported separately and not as Adverse Events

BLAZE-1 PHASE 3: ADVERSE EVENTS

MOST COMMON TREATMENT-EMERGENT ADVERSE EVENTS

N (%)	Placebo (N=517)	Bamlanivimab 2800 mg + Etesevimab 2800 mg (N=518)
Nausea	4 (0.8)	5 (1.0)
Rash	3 (0.6)	6 (1.2)
Dizziness	3 (0.6)	4 (0.8)
Diarrhea	2 (0.4)	2 (0.4)
Hypertension	2 (0.4)	2 (0.4)
Vaginal Infection	1 (0.4)	1 (0.4)
Gastroesophageal Reflux Disease	0	3 (0.6)
Pruritus	0	3 (0.6)
Urinary Tract Infection	0	3 (0.6)
Urticaria	1 (0.2)	2 (0.4)
Vomiting	1 (0.2)	2 (0.4)
Abdominal Pain	1 (0.2)	1 (0.2)
Blood Creatine Phosphokinase Increased	1 (0.2)	1 (0.2)
COVID-19	2 (0.4)	0
Constipation	1 (0.2)	1 (0.2)
Dehydration	1 (0.2)	1 (0.2)
Dysgeusia	0	2 (0.4)
Dyspepsia	0	2 (0.4)
Fungal Infection	2 (0.4)	0
Headache	1 (0.2)	1 (0.2)

BLAZE-1 PHASE 2: BAMLANIVIMAB MONOTHERAPY

EVENTS OF COVID-19 RELATED HOSPITALIZATION OR EMERGENCY ROOM VISIT WITHIN 28 DAYS AFTER TREATMENT

ALL SUBJECTS

	N	Events	Rate
Placebo	156	9	5.8%
Bamlanivimab 700 mg	101	1	1.0%
Bamlanivimab 2800 mg	107	2	1.9%
Bamlanivimab 7000 mg	101	2	2.0%
All Bamlanivimab Doses	309	5	1.6%

~72% reduction vs. placebo

AGE ≥ 65 OR BMI ≥ 35

	N	Events	Rate
Placebo	69	7	10.1%
Bamlanivimab 700 mg	46	1	2.2%
Bamlanivimab 2800 mg	46	1	2.2%
Bamlanivimab 7000 mg	44	2	4.5%
All Bamlanivimab Doses	136	4	2.9%

~71% reduction vs. placebo

BLAZE-1 PHASE 3: PRIMARY ENDPOINT

COVID-19 RELATED HOSPITALIZATION OR DEATH BY ANY CAUSE BY DAY 29

	N	Events	Rate	*p*
Placebo	517	36	7.0%	-
Bamlanivimab 2800 mg + Etesevimab 2800 mg	518	11	2.1%	0.0004

70% reduction vs. placebo

DEATH BY ANY CAUSE BY DAY 29

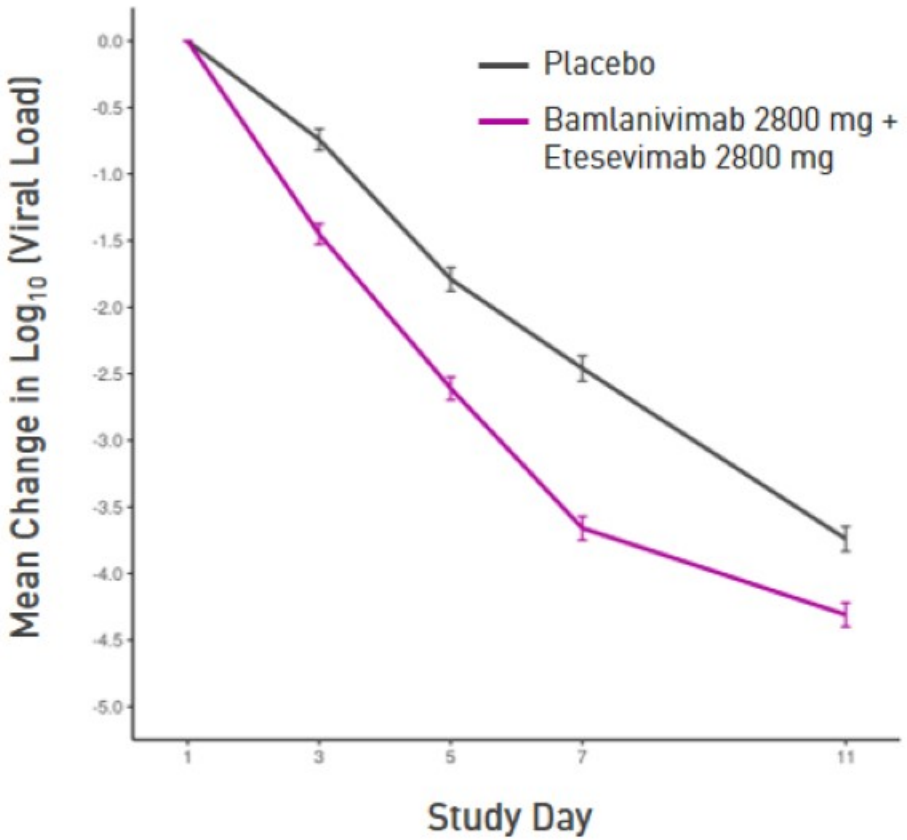
	N	Events	Rate
Placebo	517	10[†]	1.9%
Bamlanivimab 2800 mg + Etesevimab 2800 mg	518	0	0%

No deaths of any cause with antibody therapy

[†]8 of 10 deaths were deemed COVID-19 related

BLAZE-1 PHASE 3: IMPACT ON VIRAL LOAD

VIRAL LOAD CHANGE FROM BASELINE

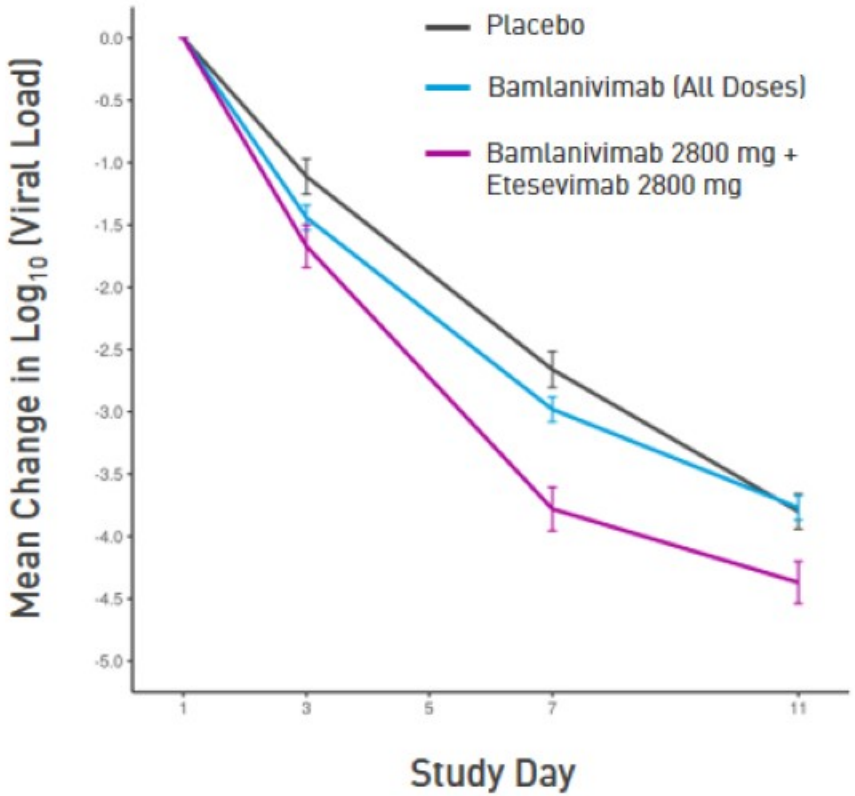


MEAN VIRAL LOAD

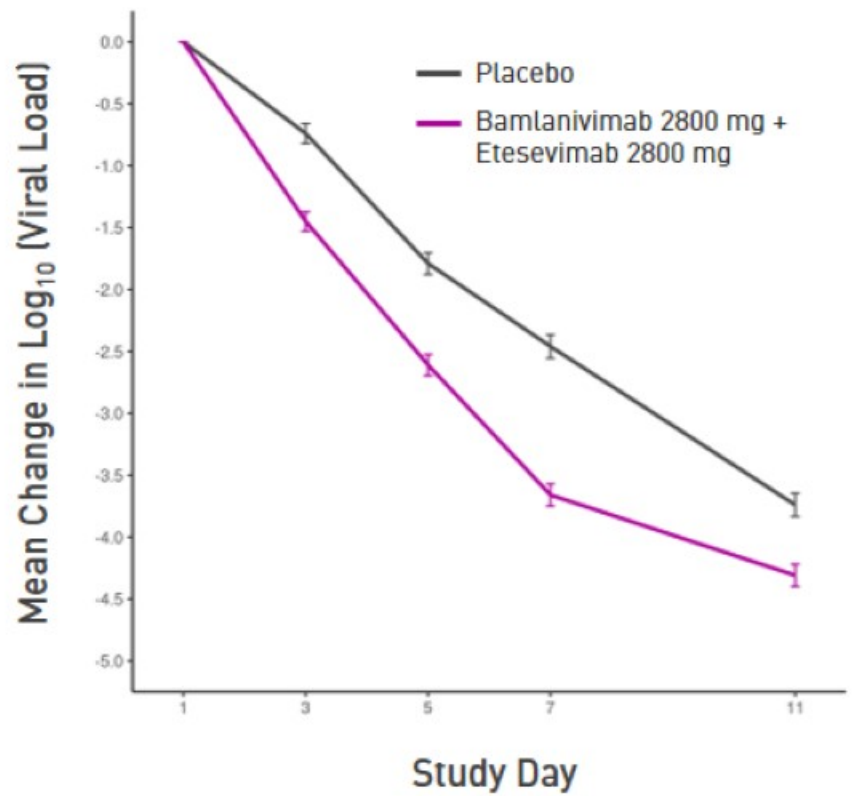
	Placebo	Bamlanivimab + Etesevimab	*p*
Day 1	6.52	6.51	-
Day 3	5.74	5.04	<0.000001
Day 5	4.68	3.85	<0.000001
Day 7	4.05	2.87	<0.000001
Day 11	2.69	2.21	0.000011

BLAZE-1: CONSISTENT IMPACT ON VIRAL LOAD

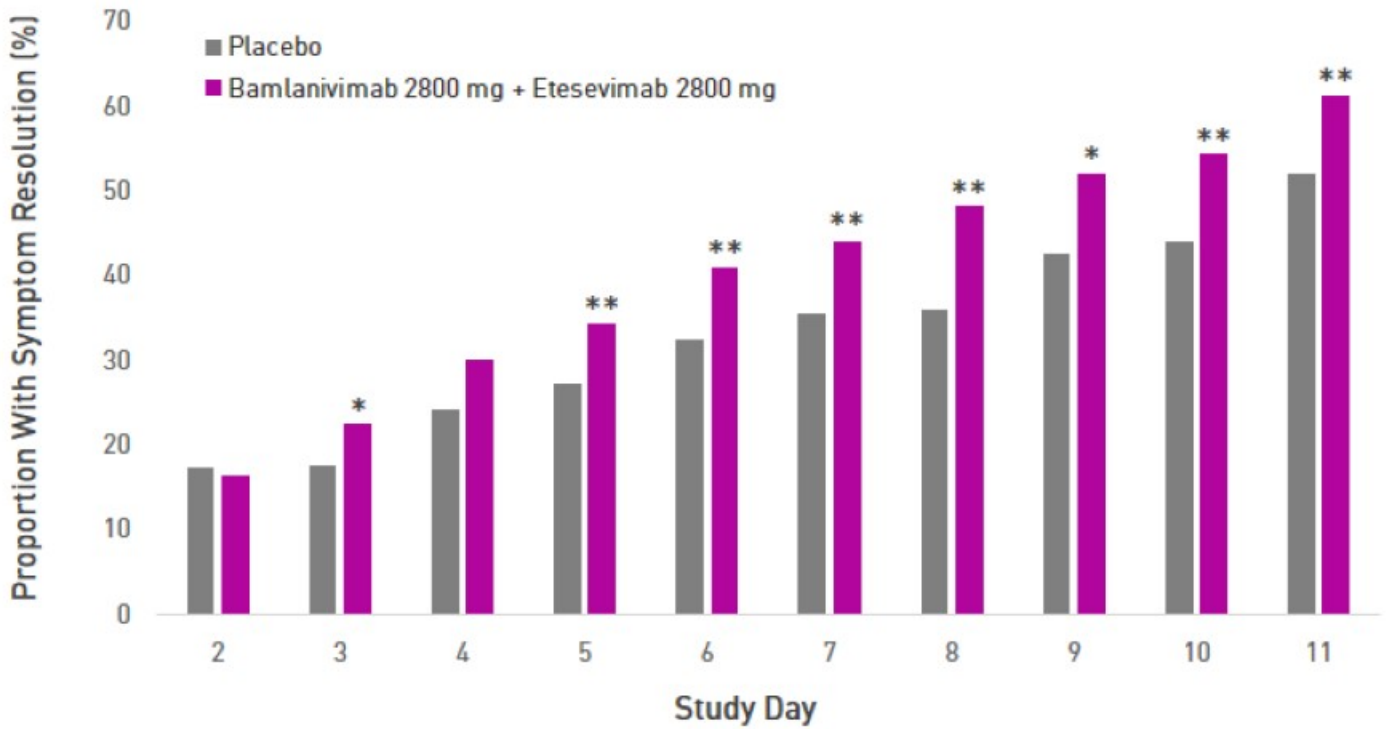
PHASE 2 PORTION



PHASE 3 PORTION



BLAZE-1 PHASE 3: SYMPTOM RESOLUTION



- Symptom resolution defined as absence of all symptoms with an allowance for mild cough or fatigue
- Early and sustained impact on symptoms was similar to that observed in Phase 2 with bamlanivimab alone and bamlanivimab + etesevimab
- Time to sustained symptom resolution (two consecutive daily assessments) was significantly improved for bamlanivimab + etesevimab vs. placebo in this study ($p = 0.007$)

*: $p < 0.05$ **: $p < 0.01$

BLAZE-1 AND BLAZE-2: COVID-19 RELATED DEATHS

BLAZE-1 PHASE 3 (AMBULATORY)		BLAZE-2 PHASE 3 (PROPHYLAXIS)	
8	Placebo	4	Placebo
0	Bamlanivimab + Etesevimab	0	Bamlanivimab

No COVID-Related Deaths With Neutralizing Antibody Therapy in These Analyses

Lilly will no longer conduct placebo-controlled studies in high-risk patients

BLAZE-1 AND BLAZE-2: SUMMARY

BLAZE-1 Phase 3 (Treatment)

- Phase 3 confirms and replicates Phase 2 findings, with 70% reduction in risk of hospitalization ($p=0.0004$), decreased viral load ($p<0.000001$), and improved sustained symptom resolution ($p=0.007$)
- Outcomes consistent with EUA for bamlanivimab alone (71% reduction in risk of hospitalization)
- No deaths due to any cause (10 vs. 0)

BLAZE-2 Phase 3 (Prophylaxis)

- Up to 80% reduction in risk of symptomatic COVID-19 in residents ($p=0.00026$)
- No COVID-related deaths in prevention population (4 vs. 0)
- No deaths due to any cause in treatment population (4 vs. 0)

NEXT STEPS

Global Availability

- Bamlanivimab is authorized for treatment use in US, Canada, Panama, Germany, Hungary, Israel, UAE, Kuwait, and Saudi Arabia
- FDA is reviewing EUA request for bamlanivimab + etesevimab (submitted Nov. 2020); intend to begin global submissions
- Plan to request EUA for bamlanivimab as post-exposure prophylaxis in US imminently

Supply

- 1 million doses of bamlanivimab shipped by end of January; ~1 million more available through mid-2021
- In partnership with Amgen, intend to manufacture ~1 million doses of bamlanivimab + etesevimab through mid-2021 (250k available in Q1)
- Preliminary BLAZE-4 data show comparable effects on viral load and symptoms with lower doses including the proposed EUA dose of 700/1400 mg

Patient Access and Ease of Use

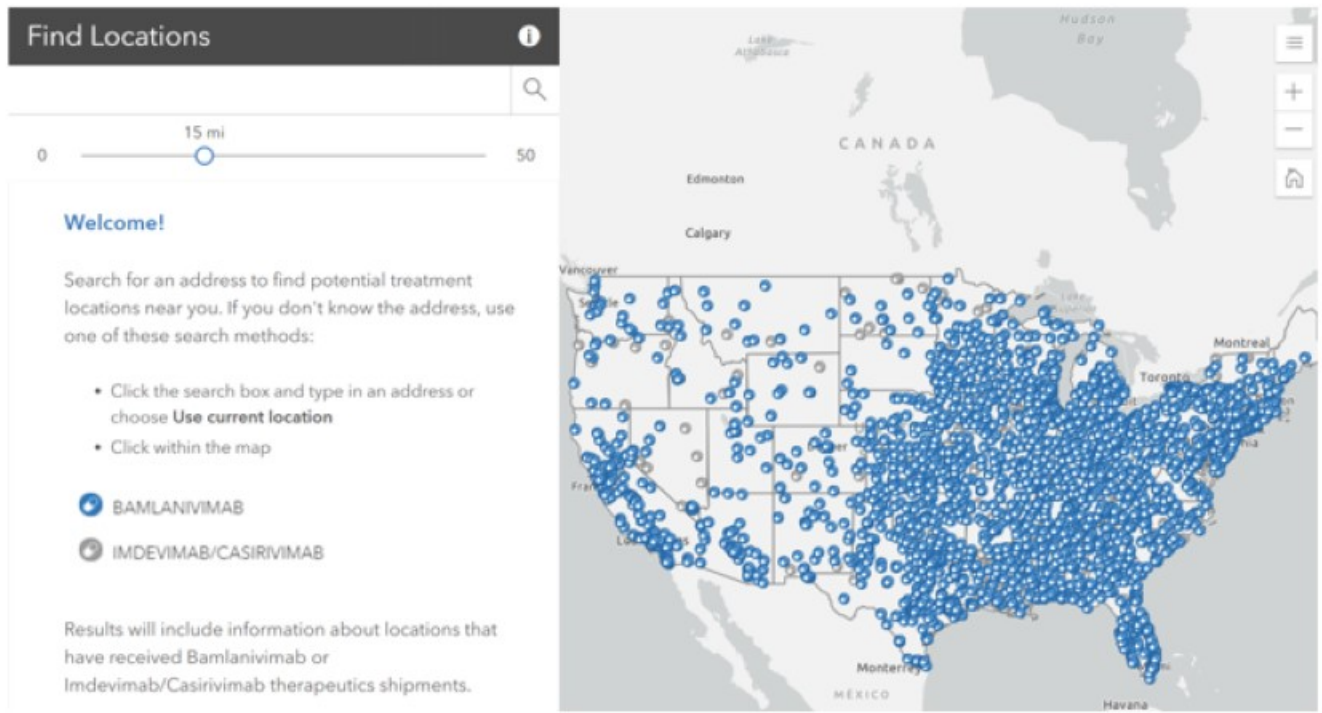
- Neutralizing antibodies are free of charge for patients wherever possible
- Submitted data to FDA supporting reduced infusion times as short as 16 minutes
- Numerous resources and partnerships to connect patients with facilities administering neutralizing antibodies

HELPING PATIENTS LOCATE TREATMENT

For more information about the use of bamlanivimab for the treatment of mild to moderate COVID-19 in high-risk patients under the FDA's emergency use authorization, contact Lilly's 24-hour support line at 1-855-LillyC19 (1-855-545-5921).

Patients and physicians can visit covid.infusioncenter.org or the HHS Therapeutics Distribution locator to find a potential treatment location, or visit combatcovid.hhs.gov to find out more about antibody therapy.

protect-public.hhs.gov/pages/therapeutics-distribution

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