SARS-CoV-2 NEUTRALIZING ANTIBODY PROGRAM UPDATE

OCTOBER 7, 2020

Agenda

Introduction
Dave Ricks, Chairman and Chief Executive Officer

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

Q&A

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 UPDATE

- Initiated program less than 7 months ago via collaborations with AbCellera/NIH and Junshi Biosciences
- Lilly submitted a request for Emergency Use Authorization (EUA) for LY-CoV555 monotherapy in higher-risk patients with recently diagnosed mild-to-moderate COVID-19
- New data from BLAZE-1 study show that combination treatment with LY-CoV555 and LY-CoV016 reduced viral load, symptoms, and COVID-related hospitalizations and ER visits; EUA request to follow
- Large scale manufacturing underway for both LY-CoV555 and LY-CoV016. As previously announced, Lilly is partnering with Amgen to significantly increase global manufacturing capacity
- Lilly is prepared to supply 1 million doses of monotherapy and 50,000 doses of combination therapy in Q4 2020; Combination supply will increase substantially in Q1 2021

LILLY SARS-CoV-2 NEUTRALIZING ANTIBODIES

	LY-CoV555	LY-CoV016
Collaborators	AbCellera NIAID (VRC)	君实生物 TopAlliance Chinese Academy of Science (IMCAS/Junshi)
Binding Site	SARS-CoV-2 RBD	SARS-CoV-2 RBD (Separate Epitope)
Class	Fully human IgG1; unmodified	Fully human IgG1; effector null
Preclinical Efficacy	Live virus assays; rodent & NHP protection	Live virus assays; NHP protection
Publication	Jones et al., manuscript under review (available on bioRxiv)	Shi et al., Nature 2020

RBD = Receptor Binding Domain
NHP = Non-Human Primate
NIAID = National Institute of Allergy and Infectious Diseases
VRC = Vaccine Research Center
IMCAS = Institute of Microbiology, Chinese Academy of Sciences

CLINICAL PROGRAM OVERVIEW

AMBULATORY (RECENTLY DIAGNOSED)

BLAZE-1

- LY-CoV555 and LY-CoV555 + LY-CoV016
- 800+ patients planned

ACTIV-2

- LY-CoV555 monotherapy
- Partnership with NIH
- 2000 patients planned

BLAZE-4

- Evaluating lower IV Doses for Combination
- Initiating soon

Planned Study

- Large pragmatic study
- Open-label, mono and combo
- Thousands of patients

POST-EXPOSURE PROPHYLAXIS

BLAZE-2

- LY-CoV555 monotherapy
- Residents and staff of long-term care facilities
- Event driven design
- Expect to enroll 1200-2400 patients

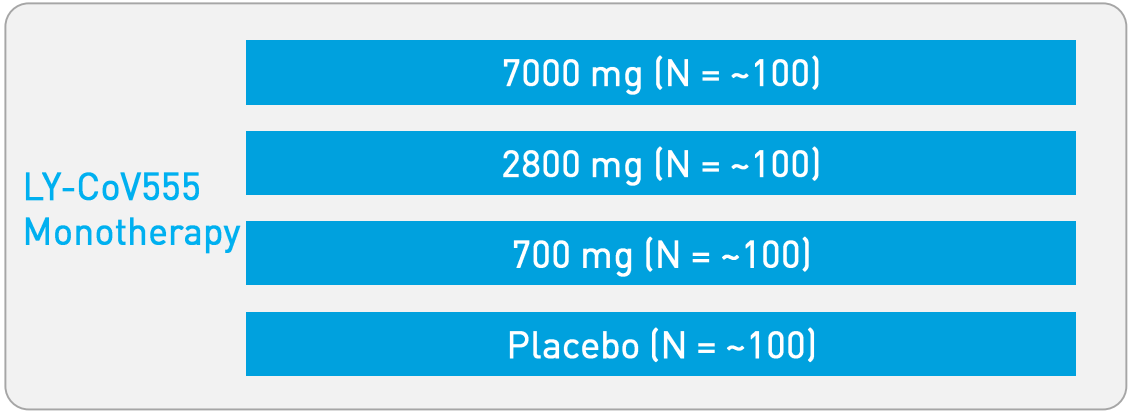
HOSPITALIZED

ACTIV-3

- LY-CoV555 monotherapy
- Partnership with NIH
- 1000 patients planned

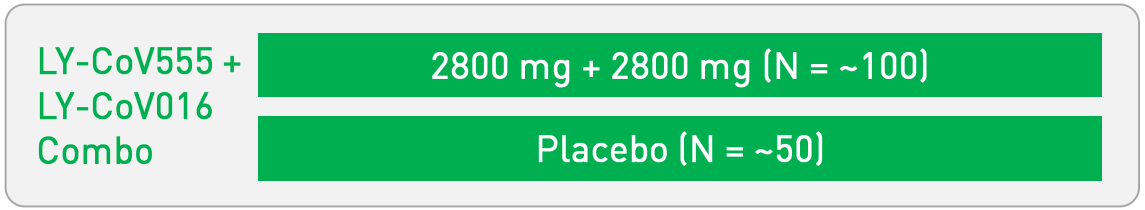
Over **850** trial participants have been dosed with LY-CoV555 (alone or in combination with LY-CoV016)

BLAZE-1 STUDY OVERVIEW



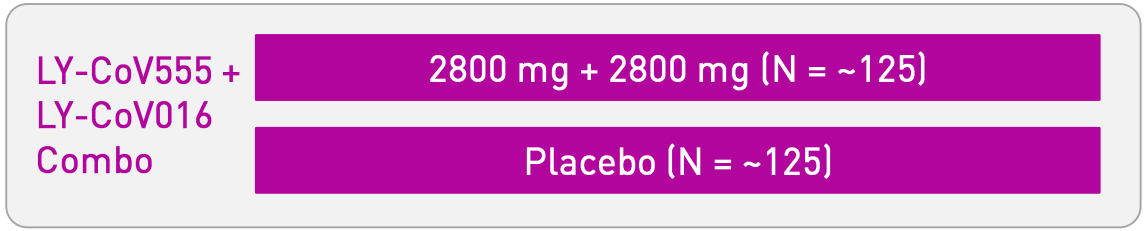
Part A

- Positive SARS-CoV-2 test ≤ 3 days prior to infusion
- Mild or moderate COVID-19 symptoms in ambulatory setting
- Primary Endpoint: Change from baseline to Day 11 (± 4 days) in SARS-CoV-2 viral load
- Secondary endpoints include safety, symptom severity, hospitalization, alternate measures/time points for viral clearance



Part B

- Same population / endpoint as Part A
- Placebo pooled with concurrent placebo from Part A



Part C

- Enrolling patients at high risk for COVID-19 complications
- To be analyzed separately

BASELINE CHARACTERISTICS

BASELINE DEMOGRAPHICS AND DISEASE CHARACTERISTICS (SAFETY POPULATION)

	Placebo (N=156)	LY-CoV555 Mono (All Doses) (N=309)	LY-CoV555 + LY-CoV016 (N=112)
Female	54.5%	55.7%	51.8%
Hispanic or Latino	43.6%	43.7%	37.5%
Black or African American	4.6%	7.2%	3.6%
Age (median)	46.0	45.0	43.5
Age ≥65	14.7%	10.7%	11.6%
BMI (mean)	30.1	30.1	28.8
BMI ≥40	5.9%	7.9%	6.4%
High-Risk Status for Severe COVID-19 Illness[1]	67.3%	69.6%	59.8%
Mild COVID-19	79.5%	75.1%	82.1%
Duration of Symptoms (days, mean)	4.6	4.7	4.5
Mean Symptom Score[2]	6.6	6.7	6.2

[1]Age>=55, or BMI>=30, or at least one medical history with preferred terms

[2]Efficacy population

LY-CoV555 Mono is pooled data from 700 mg, 2800 mg, and 7000 mg

SAFETY AND TOLERABILITY

SUMMARY OF ADVERSE EVENTS

N (%)	Placebo (N=156)	LY-CoV555 Mono (All Doses) (N=309)	LY-CoV555 + LY-CoV016 (N=112)
TEAEs	41 (26.3)	71 (23.0)	15 (13.4)
TEAEs by severity			
Mild	21 (13.5)	43 (13.9)	11 (9.8)
Moderate	17 (10.9)	18 (5.8)	3 (2.7)
Severe	3 (1.9)	9 (2.9)	1 (0.9)
Deaths	0	0	0
SAEs	1 (0.6)	0	1* (0.9)

*Urinary tract infection requiring hospitalization, deemed unrelated to study drug

- Monotherapy and combination both generally well tolerated; no significant safety concerns
- No clinically meaningful differences in TEAEs were observed across treatment groups
- Study-specific clinical events related to COVID-19 reported separately and not as Adverse Events (per protocol)

AE = Adverse Event
SAE = Serious Adverse Event; TEAE = Treatment-Emergent Adverse Event
LY-CoV555 Mono is pooled data from 700 mg, 2800 mg, and 7000 mg

SAFETY AND TOLERABILITY

TEAEs OCCURRING IN ≥ 1% OF ALL PATIENTS

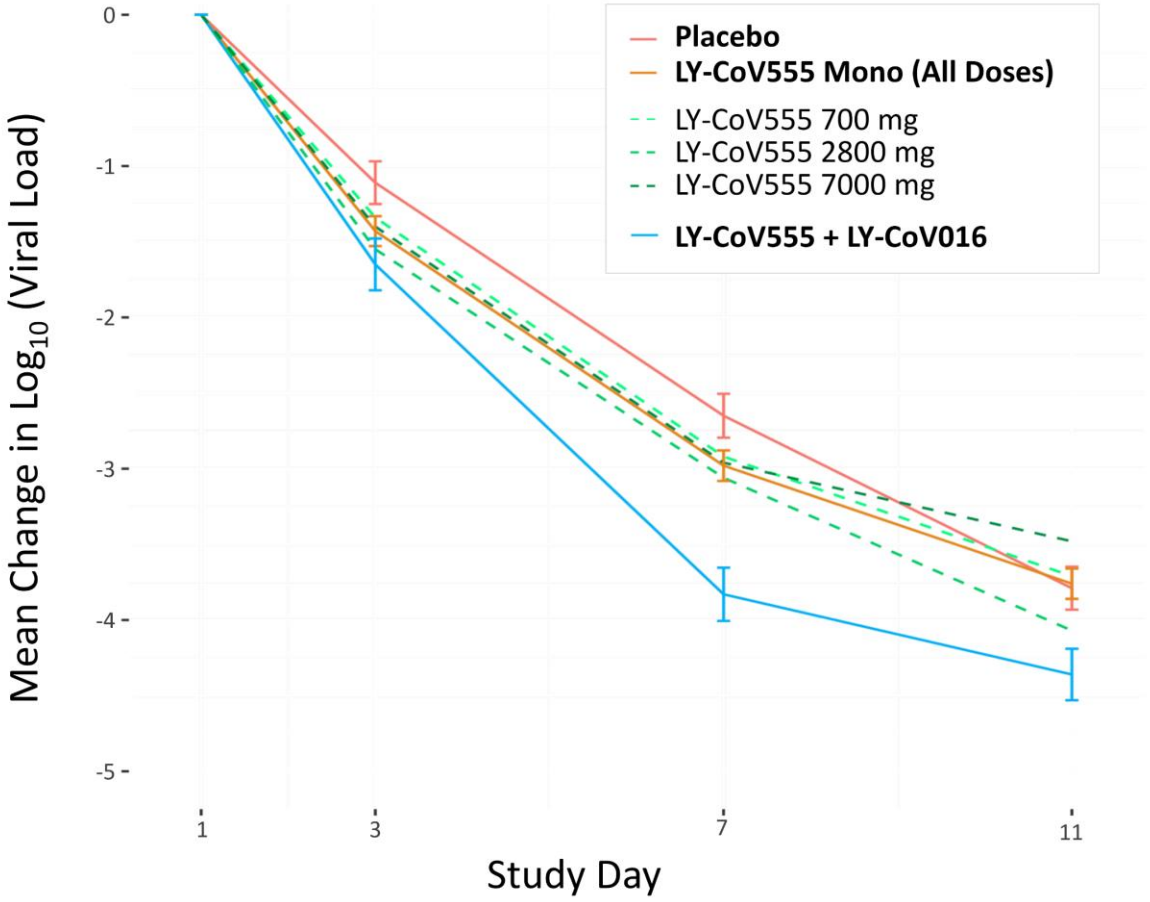
N (%)	Placebo (N=156)	LY-CoV555 Mono (All Doses) (N=309)	LY-CoV555 + LY-CoV016 (N=112)
Nausea	6 (3.8)	12 (3.9)	3 (2.7)
Diarrhea	8 (5.1)	10 (3.2)	1 (0.9)
Dizziness	3 (1.9)	9 (2.9)	0
Headache	3 (1.9)	5 (1.6)	1 (0.9)
Pruritus	1 (0.6)	5 (1.6)	2 (1.8)
Vomiting	4 (2.6)	5 (1.6)	1 (0.9)

TEAE = treatment-emergent adverse event
LY-CoV555 Mono is pooled data from 700 mg, 2800 mg, and 7000 mg

- No clinically meaningful differences in TEAEs were observed across treatment groups
- The majority of TEAEs were mild to moderate in severity

IMPACT ON VIRAL LOAD

VIRAL LOAD CHANGE FROM BASELINE



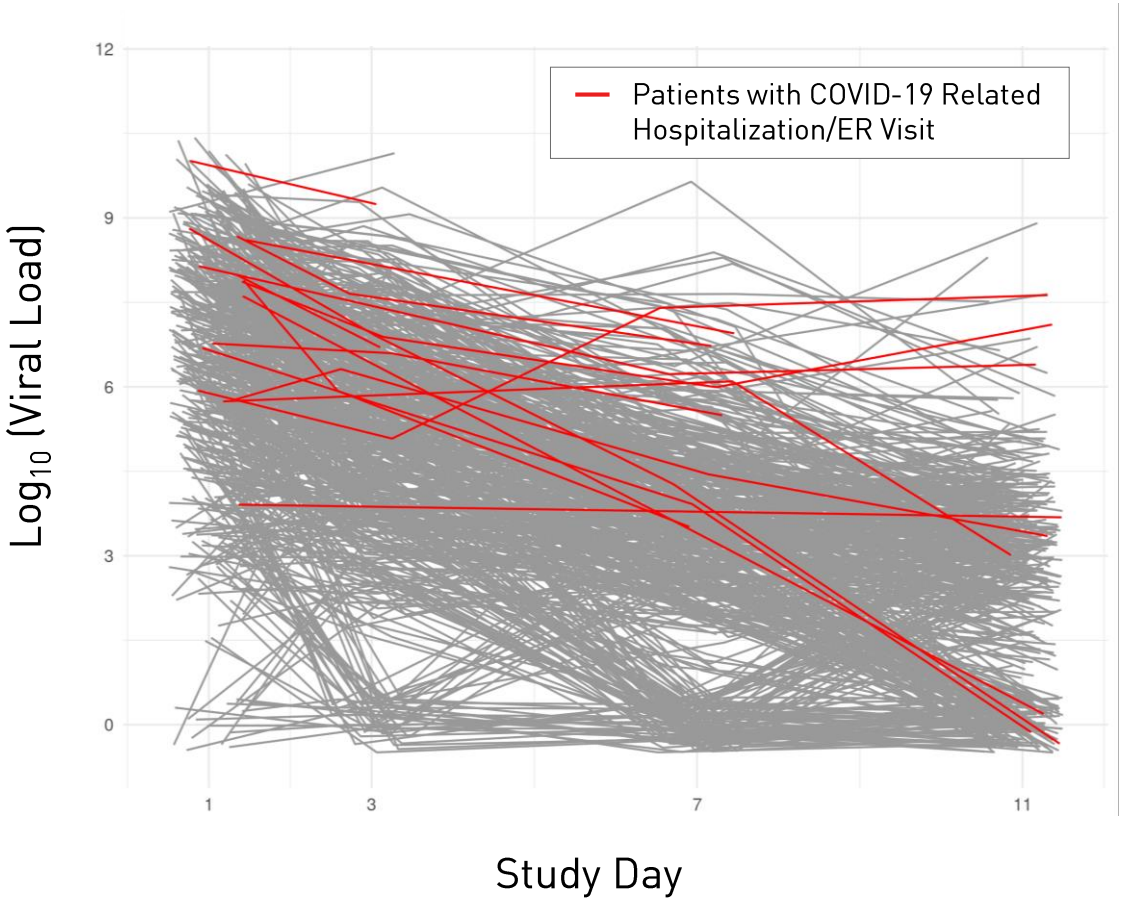
PRE-SPECIFIED ANALYSIS

	Δ vs. PBO	*p*	
LY Mono	0.03 (0.17)	0.87	Day 11 Primary Endpoint
LY Combo	−0.56 (0.22)	0.011	
LY Mono	-0.32 (0.17)	0.065	Day 3
LY Combo	−0.54 (0.22)	0.016	
LY Mono	-0.33 (0.18)	0.063	Day 7
LY Combo	−1.18 (0.23)	<0.001	
LY Mono	-1.52 (1.34)	0.26	AUC Day 1-11
LY Combo	-6.50 (1.66)	<0.001	

Table values are mean (standard deviation)
LY-CoV555 Mono is pooled data from 700 mg, 2800 mg, and 7000 mg

PERSISTENTLY HIGH VIRAL LOAD IS ASSOCIATED WITH HOSPITALIZATION + ER VISITS

VIRAL LOAD OVER TIME (ALL PATIENTS)



HOSPITALIZED VS. NON-HOSPITALIZED PATIENTS

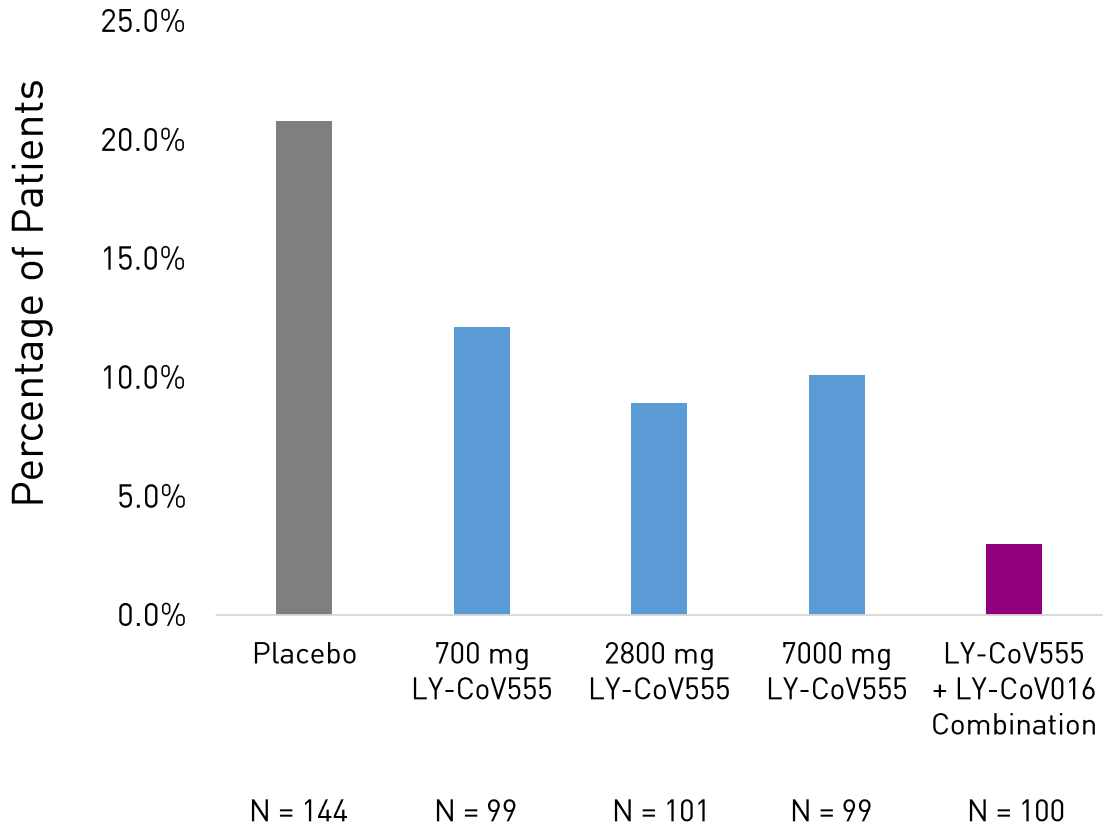
Wilcoxon Rank-Sum Test:

- Day 1 viral load: p=0.15
- Day 3 viral load: p=0.0053
- Day 7 viral load: p=0.00011

post-hoc analysis, not adjusted for multiplicity

RATE OF PHVL[1] BY DOSE

LOG(VIRAL LOAD) ≥ 5.27 @ DAY 7



PHVL BY DOSE

	%	*p**
Placebo	20.8%	-
700 mg LY-CoV555	12.1%	0.086
2800 mg LY-CoV555	8.9%	0.013
7000 mg LY-CoV555	10.1%	0.034
LY-CoV555 Mono (All Doses)	10.4%	0.0048
LY-CoV555 + LY-CoV016 Combo	3.0%	0.000036

*Fisher's exact test. Post-hoc analysis, not adjusted for multiplicity

[1]PHVL (Persistently High Viral Load) is defined as Log(viral load) ≥ 5.27. This cut-point was determined based on pooled hospitalization and viral load data from the LY-CoV555 monotherapy cohort, prior to receipt of combination data. Ongoing cohorts incorporate this measure as a prespecified endpoint.

COVID-19 RELATED HOSPITALIZATION OR ER VISIT

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

ALL SUBJECTS

	N	Events	Rate	*p*
Placebo	156	9	5.8%	-
LY Mono (All Doses)	309	5	1.6%	0.020
LY Combo	112	1	0.9%	0.049
LY Mono + Combo	421	6	1.4%	0.0067

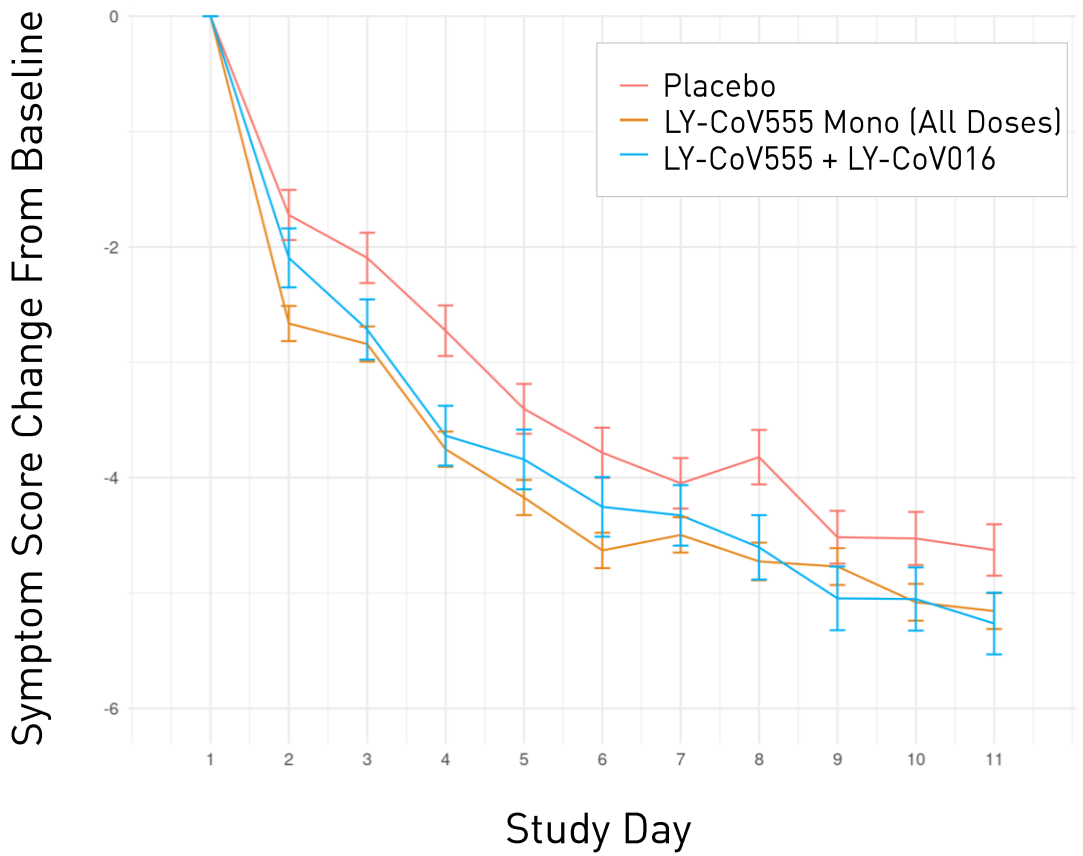
AGE ≥ 65 OR BMI ≥ 35

	N	Events	Rate
Placebo	52	7	13.5%
LY Mono (All Doses)	101	4	4.0%
LY Combo	31	0	0%
LY Mono + Combo	132	4	3.0%

BMI = Body Mass Index; ER = Emergency Room
P-values are from the Fisher's exact test
LY-CoV555 Mono is pooled data from 700 mg, 2800 mg, and 7000 mg

IMPACT ON SYMPTOMS

SYMPTOM SCORE CHANGE FROM BASELINE



PRE-SPECIFIED ANALYSIS: AUC (DAY 1-11)

	Δ vs. PBO	*p*
700 mg LY-CoV555	−7.90 (3.01)	0.009
2800 mg LY-CoV555	−6.35 (3.05)	0.038
7000 mg LY-CoV555	−7.86 (3.09)	0.011
LY-CoV555 Mono (All Doses)	−7.38 (2.51)	0.004
LY-CoV555 + LY-CoV016 Combo	−8.08 (3.10)	0.009

AUC = Area Under the Curve
Table values are mean (standard deviation)
LY-CoV555 Mono is pooled data from 700 mg, 2800 mg, and 7000 mg

BLAZE-1 SUMMARY

- LY-CoV555 monotherapy and LY-CoV555 + LY-CoV016 combination were generally well tolerated at all doses
- Trial was designed primarily as a safety and biomarker study; however meaningful clinical efficacy signals emerged
- Combination Therapy Viral Endpoints
  - Primary endpoint of change from baseline in viral load at Day 11 was met
  - Secondary endpoints of reduced viral load at Day 3 and Day 7, as well as time-weighted average change from baseline for Day 1 to 11 were met
  - Exploratory analyses show a reduction in the % of patients with persistently high viral load at Day 7
  - Exploratory analyses show <1% putative resistance variants (vs. ~7% in placebo, ~9% in monotherapy)
- Combination Therapy Clinical Endpoints
  - Secondary endpoint of reducing rate of COVID-related hospitalizations and ER visits was met for combination vs. placebo, similar to monotherapy
  - Secondary analysis of change in mean symptom score (Day 1-11) was met for combination vs. placebo, similar to monotherapy

Combination therapy appears more efficacious on viral endpoints.
Both monotherapy and combination therapy show similar improvements on clinical endpoints.

NEXT STEPS

CLINICAL

- BLAZE-1 remains ongoing, enrolling a confirmatory cohort of higher risk patients
- Interim results will be published in peer reviewed journal(s)
- Plan to initiate a large, open-label pragmatic study of mono and combo
- Study evaluating lower doses of combo will begin soon
- Registration studies ongoing: Treatment of hospitalized patients, Prophylaxis in nursing home residents and staff

REGULATORY

- Request for Emergency Use Authorization (EUA) for LY-CoV555 monotherapy in higher risk patients has been submitted
- Expect to submit combination EUA in November once additional safety data accumulate and sufficient supply is manufactured
- Anticipate BLA submission for combination therapy as early as Q2 2021
- Discussions with global regulators are ongoing

SUPPLY

- Large scale manufacturing underway for both LY-CoV555 and LY-CoV016
- Able to supply 1 million doses of LY-CoV555 monotherapy (700 mg) in Q4 2020
- Combination supply is more limited with approximately 50,000 doses available in Q4
- Combination supply increases substantially in Q1 2021 as additional manufacturing resources come online throughout the year, including Amgen collaboration
- Pursuing additional partnerships to provide antibodies to resource-limited countries


Lilly