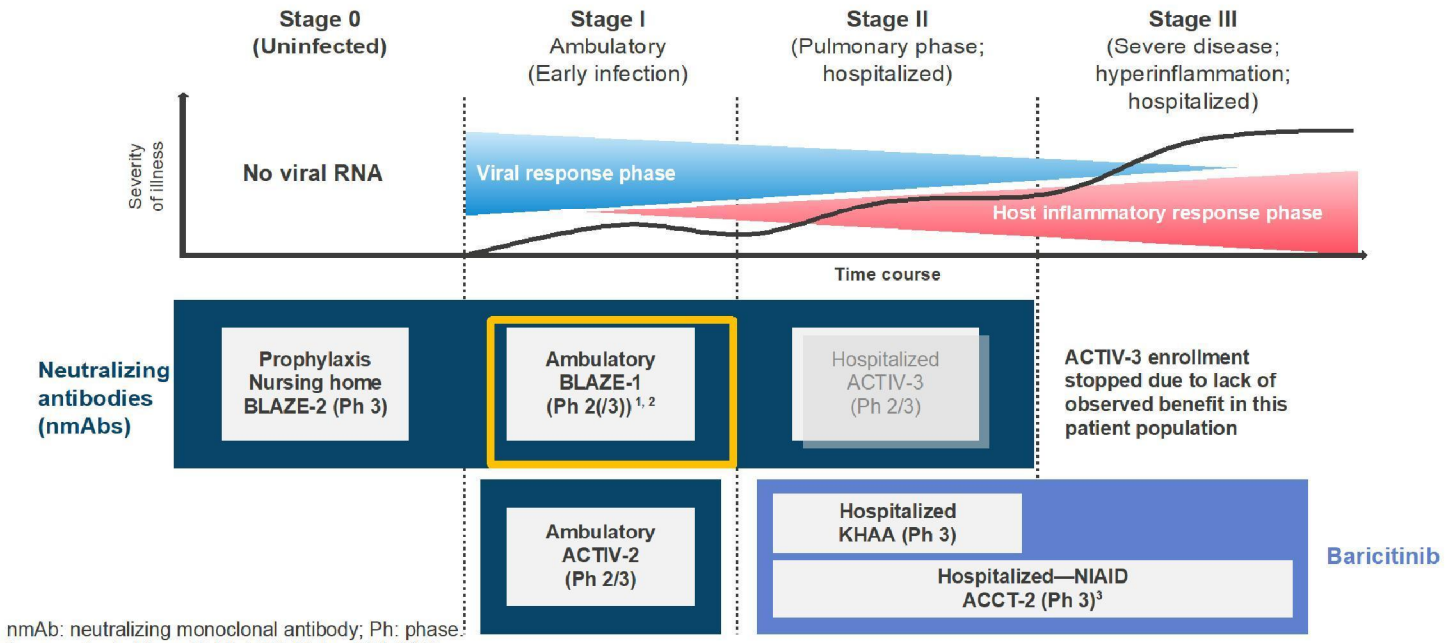
Investigational Products Currently in (or Planned for) Clinical Trials



nmAb: neutralizing monoclonal antibody; Ph: phase.
Image adapted from Siddiqi HK, Mehra RM, 2020.

1. Chen P, et al. N Engl J Med. 2020. doi:10.1056/NEJMoa2029849; 2. Gottlieb RL et al. JAMA 2021; doi:10.1001/jama.2021.0202 3. Kalil AC et al. NEJM 2020; doi: 10.1056NEJMoa2031994

BLAZE-1 Ambulatory Setting; 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)

Adapted from: SARS-CoV-2 Neutralizing Antibody Program Update Presentation, January 26, 2021, https://investor.lilly.com/static-files/e0ef0ef0-f4e0-f4e0-b0d2-7ae4daf9e953

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BLAZE-1 Phase 2; Bamlanivimab Monotherapy

Covid-19 Related Hospitalization or ER 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

Adapted from: SARS-CoV-2 Neutralizing Antibody Program Update Presentation; January 26, 2021; https://investor.lilly.com/static-files/081a5ef7-f5d6-4acc-b0d2-7ae4daf9e953

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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

Adapted from: SARS-CoV-2 Neutralizing Antibody Program Update Presentation; January 26, 2021; https://investor.lilly.com/static-files/081a5ef7-f5d6-4acc-b0d2-7ae4daf9e953

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Bamlanivimab Emergency Use Authorization and Administration Guidance

BAMLANIVIMAB MUST BE ADMINISTERED BY INTRAVENOUS (IV) INFUSION

Health care providers must submit a report on all medication errors and **ALL SERIOUS ADVERSE EVENTS** related to bamlanivimab.

Bamlanivimab may be used for the **treatment of mild-to-moderate COVID-19 in adults and pediatric patients** with positive results of direct SARS-CoV-2 viral testing who are ≥ 12 years of age weighing at least 40 kg, and **who are at high-risk** for progressing to severe COVID-19 and/or hospitalization.

Bamlanivimab should not be used in patients hospitalized or who require oxygen due to COVID-19 respiratory disease.

www.bamlanivimabhcpinfo.com

High risk is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) ≥ 35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥ 65 years of age
- Are ≥ 55 years of age **AND** have
  - CVD **OR** hypertension **OR** COPD/other chronic respiratory disease
- Are 12-17 years of age **AND** have
  - BMI ≥85th percentile for their age and gender **OR** sickle cell disease **OR** congenital/acquired heart disease **OR** neurodevelopmental disorders **OR** medical-related technological dependence **OR** asthma/reactive airway/chronic respiratory disease that requires daily medication control

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