COVID-19 monoclonal antibody side-by-side comparison

Updated: January 12, 2022

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Summary of changes since last publication (update: January 12, 2022)

- Updated information of the frequency of resistant variants (side-by-side comparison).
- Updated activity of the available monoclonal antibodies against the Omicron (B.1.1.529) variant (evidence summary).
- Updated individual component results of the composite endpoint from the COMET-ICE trial (evidence summary).

COVID-19 monoclonal antibody: Side-by-side comparison

	Generic name (investigational name) (brand name)			
	Bamlanivimab (LY-Co555) and Etesevimab (LY-CoV016)	**Casirivimab (REGN10933) and Imdevimab (REGN10987) (REGEN-COV)**	**Sotrovimab (VIR-7831)**	**Tixagevimab (AZD8895) and Cilgavimab (AZD1061) (AZD7442) (Evusheld)**
Manufacturer	Eli Lilly	Regeneron	GlaxoSmithKline	AstraZeneca
EUA approved indication(s)				
Pre-exposure prophylaxis	--	--	--	Pre-exposure prophylaxis in adult and pediatric patients (≥ 12 y and ≥ 40 kg).
Outpatient treatment	Treatment of mild-to-moderate COVID-19 in adults and pediatric patients, including neonates.	Treatment of mild-to-moderate COVID-19 in adults and pediatric patients (≥ 12 y and ≥ 40 kg).		--
Post-exposure prophylaxis	Post-exposure prophylaxis in adults and pediatric patients, including neonates.	Post-exposure prophylaxis in adults and pediatric patients (≥ 12 y and ≥ 40 kg).	--	--
Criteria for use				
Pre-exposure prophylaxis (tixagevimab/cilgavimab)				
• Individuals who are <u>not</u> currently infected with SARS-CoV-2 and who have <u>not</u> had a known recent exposure to an individual infected with SARS-CoV-2, and ○ Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination, or ○ For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (eg, severe allergic reaction) to a COVID-19 vaccine(s) and /or COVID-19 vaccine component(s).			
Outpatient treatment (bamlanivimab/etesevimab, casirivimab/imdevimab, sotrovimab)				
Individuals with positive results of direct SARS-CoV-2 viral testing, and who are at high risk (*see high risk criteria in EUA*) for progression to severe COVID-19, including hospitalization or death.				
Post-exposure prophylaxis (bamlanivimab/etesevimab, casirivimab/imdevimab)				
• Individuals who are at high risk (*see high risk criteria in EUA*) for progressing to severe COVID-19, including hospitalization or death and are not fully vaccinated or not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination, and ○ Who have been exposed to an individual infected with SARS-CoV-2 consistent with the close contact criteria per CDC, or ○ Who are at high risk of exposure to an individual infected with SARS-CoV-2 because of an occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting.				

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	Bamlanivimab (LY-Co555) and Etesevimab (LY-CoV016)	**Casirivimab (REGN10933) and Imdevimab (REGN10987) (REGEN-COV)**	**Sotrovimab (VIR-7831)**	**Tixagevimab (AZD8895) and Cilgavimab (AZD1061) (AZD7442) (Evusheld)**
Limitations for use				
Pre-exposure prophylaxis (tixagevimab/cilgavimab)				
• Not authorized for use in individuals: for treatment of COVID-19, or for post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2. • Pre-exposure prophylaxis is not a substitute for vaccination against COVID-19. • Tixagevimab and cilgavimab should be administered at least two weeks after the COVID-19 vaccine.				
Outpatient treatment (bamlanivimab/etesevimab, casirivimab/imdevimab, sotrovimab)				
• Not authorized for use in individuals: who are hospitalized due to COVID-19, or who require oxygen therapy due to COVID-19, or who require an increase in baseline oxygen flow rate due to COVID-19 (in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity). • Benefit of treatment has not been observed in patients hospitalized due to COVID-19. SARS-CoV-2 monoclonal antibodies may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.				
Post-exposure prophylaxis (bamlanivimab/etesevimab, casirivimab/imdevimab)				
• Post-exposure prophylaxis is not a substitute for vaccination against COVID-19. • Not authorized for pre-exposure prophylaxis for prevention of COVID-19.				
Frequency of resistant variants				
• Current variant frequency information is available from the CDC Nowcast. • Sotrovimab, and tixagevimab and cilgavimab are reported to retain activity against the Omicron variant (see Resistance section). • Bamlanivimab and etesevimab, and casirivimab and imdevimab are unlikely to retain activity against the Omicron variant (see Resistance section). • All states and territories can continue to order bamlanivimab and etesevimab, and casirivimab and imdevimab based on the variability in prevalence of the Omicron variant.[e]				

<table>
<tr><th colspan="5">Mechanism of action</th></tr>
<tr><td>Pharmacology</td><td>Bamlanivimab and etesevimab are IgG1 mAbs that neutralize the spike protein of SARS-CoV-2, which can block the spike protein attachment to human ACE2 receptors, thus preventing subsequent viral entry into human cells and viral replication.</td><td>Casirivimab (IgG1κ) and imdevimab (IgG1λ) are recombinant human mAbs, unmodified in the Fc regions. Casirivimab and imdevimab bind to non-overlapping epitopes of the spike protein receptor binding domain (RBD) of SARS-CoV-2. Casirivimab plus imdevimab blocked the RBD binding to human ACE2.</td><td>Sotrovimab (IgG1κ) is a recombinant human mAb which is modified in the Fc region, including M428L and N434S amino acid substitutions. Sotrovimab binds to a conserved epitope on the spike protein receptor binding domain of SARS-CoV-2 but does not compete with human ACE2 receptor binding.</td><td>Tixagevimab and cilgavimab are recombinant human IgG1κ mAbs with amino acid substitutions to extend antibody half-life, reduce antibody effector function, and minimize the potential risk of antibody-dependent enhancement of disease. Tixagevimab and cilgavimab can simultaneously bind to non-overlapping regions of the RBD of SARS-CoV-2 spike protein.</td></tr>
<tr><th colspan="5">Dose</th></tr>
<tr><td>Specific to EUA indication(s)</td><td>Outpatient treatment
For adults (≥ 18 y) and pediatric patients < 18 y and ≥ 40 kg) the recommended dose is 700 mg bamlanivimab and 1,400 mg etesevimab given together as a single IV infusion.
For pediatric patients < 40 kg:<table><tr><th>Weight (kg)</th><th>Dose of bamlanivimab and etesevimab</th></tr><tr><td>> 20 to < 40</td><td>350 mg and 700 mg</td></tr><tr><td>> 12 to 20</td><td>175 mg and 350 mg</td></tr><tr><td>1 to 12</td><td>12 mg/kg and 24 mg/kg</td></tr></table>
Administer as soon as possible after positive results of direct SARS-CoV-2 viral testing and within 10 d of symptom onset.
Post-exposure prophylaxis
See dose for outpatient treatment of COVID-19; administer as a single IV infusion as soon as possible</td><td>Outpatient treatment
The recommended dose is 600 mg of casirivimab and 600 mg of imdevimab given together (1,200 mg) as a single IV infusion or as 4 SC injections; administer as soon as possible after positive results of SARS-CoV-2 and within 10 d of symptom onset.
SC injection is an alternative route of administration when IV infusion is not feasible and would lead to delay in treatment.
Post-exposure prophylaxis
The recommended initial dose is 600 mg of casirivimab and 600 mg of imdevimab given together (1,200 mg); administer as a single IV infusion or SC injection as soon as possible following exposure to SARS-CoV-2.
If an additional dose is required, the dose is 300 mg of casirivimab and 300 mg as a single IV infusion or 2 SC injections.</td><td>Outpatient treatment
The recommended dose is 500 mg of sotrovimab given as a single IV infusion; administer as soon as possible after positive results of SARS-CoV-2 and within 10 d of symptom onset.</td><td>Pre-exposure prophylaxis
The recommended dose is 150 mg of tixagevimab and 150 mg of cilgavimab administered as 2 separate consecutive IM injections.
Repeat dosing: Individuals who qualify for tixagevimab and cilgavimab, per conditions of the EUA, can be redosed every 6 mo.</td></tr>
</table>

	following exposure to SARS-CoV-2.	• Either IV infusion or SC injection can be used.		
Dosage adjustments	• The dose is weight based for pediatrics weighing < 40 kg. • No dosage adjustment is required in pregnancy or lactation, pediatrics ≥ 40 kg, renal impairment, or mild hepatic impairment.	No dosage adjustment is required in pregnancy or lactation, pediatrics ≥ 12 y and ≥ 40 kg, or renal impairment.		No dosage adjustment is required in pregnancy or lactation, in geriatrics, or renal impairment.
Preparation and administration				
Preparation	*Adults (≥ 18 y) and pediatric patients (< 18 y and weighing ≥ 40 kg):* *IV infusion* • Remove 1 vial of bamlanivimab and 2 vials of etesevimab from refrigerated storage and bring to room temperature for 20 mins. Do not expose to direct heat or shake the vial. • Withdraw 20 mL from 1 bamlanivimab vial and 40 mL from 2 etesevimab vials and inject all 60 mL into a prefilled infusion bag containing 0.9% sodium chloride (may use prefilled 50 mL, 100 mL, 150 mL, or 250 mL infusion bags). • Gently invert the bag by hand approximately 10 times to mix. Do not shake. *Pediatric patients (< 18 y and weighing < 40 kg):* *IV infusion and Syringe pump*	• There are 2 formulations available: a co-formulated solution (1:1 ratio) or individual antibody solutions. • Remove from refrigerated storage and bring to room temperature for 20 mins. Do not expose to direct heat or shake the vial. *IV infusion* • Withdraw 10 mL from 1 co-formulated vial or 5 mL of casirivimab and imdevimab from each respective vial and inject into a prefilled infusion bag containing 0.9% sodium chloride or 5% dextrose (may use prefilled 50 mL, 100 mL, 150 mL, or 250 mL infusion bags). • Gently invert infusion bag by hand approximately 10 times to mix. Do not shake. *SC injection*	*IV infusion* • Remove 1 vial of sotrovimab from refrigerated storage and bring to room temperature, protected from light, for 15 mins. Gently swirl the vial several times before use without creating air bubbles. Do not shake the vial. • Withdraw 8 mL of sotrovimab and inject all 8 mL into a prefilled infusion bag containing 0.9% sodium chloride (may use prefilled 50 mL or 100 mL infusion bags). • Gently rock the infusion bag back and forth by hand 3 to 5 times. Do not invert the infusion bag.	*IM injection* • Remove 1 vial of tixagevimab and 1 vial of cilgavimab from the carton. Do not shake the vials. • Withdraw 1.5 mL of tixagevimab solution and 1.5 mL of cilgavimab solution into 2 separate syringes. Discard unused portion in vials.

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Remove bamlanivimab and etesevimab vials from refrigerated storage and bring to room temperature for 20 mins. Do not expose to direct heat or shake the vial.
Withdraw the appropriate amounts of bamlanivimab and etesevimab based on body weight and inject into an empty 50-mL polyvinyl chloride (PVC) or polyethersulfone (PE)-lined PVC infusion bag, or draw into a disposable syringe for syringe pump administration.
Gently invert the infusion bag or syringe to mix the contents. Do not shake or vigorously agitate.

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Withdraw 2.5 mL, using a 21-gauge transfer needle, into a total of 4 syringes (3 mL or 5 mL polypropylene Luer Lock)

Using co-formulated vial: withdraw 2.5 mL into 4 separate syringes
Using individual vials: withdraw 2.5 mL of casirivimab into 2 syringes and 2.5 mL of imdevimab into 2 syringes

For post-exposure prophylaxis repeat dosing: Withdraw 2.5 mL, using a 21-gauge transfer needle, into a total of 2 syringes (3 mL or 5 mL polypropylene Luer Lock)

Using co-formulated vial: withdraw 2.5 mL into 2 separate syringes
Using individual vials: withdraw 2.5 mL of casirivimab into 1 syringe and 2.5 mL of imdevimab into 1 syringe

Replace the 21-gauge transfer needle with a 25-gauge or 27-gauge needle for SC injection.

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<td>Administration</td>
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Adults (≥ 18 y) and pediatric patients (< 18 y and weighing ≥ 40 kg):
IV infusion

Use of an in-line or add-on 0.20/0.22-micron PES filter is strongly recommended.
Attach the infusion set (PVC or PE-lined PVC) to the infusion bag.
The maximum infusion rate is 310 mL/h regardless of weight except for the 250 mL bag size.

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IV infusion

Use of an in-line or add-on 0.20-micron PES filter is recommended.
Attach the infusion set (PVC, PE-lined PVC, or polyurethane) to the IV bag.
Minimum infusion times for 600 mg of casirivimab and 600 mg of imdevimab for IV infusion are:

<table>
<tr><th>Prefilled 0.9% NaCl or 5% dextrose infusion bag</th><th>Minimum infusion time</th></tr>
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IV infusion

Use of an in-line or add-on 0.20-micron PES filter is recommended.
Attach the infusion set (PVC or polyolefin) to the IV bag. Prime the infusion set with 0.9% sodium chloride.
Administer the entire infusion bag over 30 mins. Due to potential overfill of prefilled saline bags, the entire infusion solution in the bag should be

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IM injection

Administer the 2 syringes consecutively.
Administer the IM injections at different sites, preferably 1 in each gluteal muscle.
Observe for 1 h after administration.

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- For the 250 mL bag size, the maximum infusion time is 310 mL/h for patients weighing ≥ 50 kg and 266 mL/h for patients ≥ 40 kg and < 50 kg.
- The minimum infusion times are:

Prefilled 0.9% NaCl infusion bag	Minimum infusion time
50 mL	21 min
100 mL	31 min
150 mL	41 min
250 mL for patients > 50 kg	60 min
250 mL for patients ≥ 40 kg and < 50 kg	70 min

- Once the infusion is complete, flush the tubing with 0.9% sodium chloride to ensure delivery of required dose.
- Observe for 1 h after infusion.

Pediatric patients (< 18 y and weighing < 40 kg):
IV infusion

- Use of an in-line or add-on 0.20/0.22-micron PES) filter.
- Attach the infusion set (PVC or PE-lined PVC) to the IV bag and prime the infusion set.
- Administer the entire infusion solution via pump or gravity over at least 16 min.
- Once the infusion is complete, flush the tubing with 0.9% sodium chloride to ensure delivery of required dose.
- Observe for 1 h after infusion.

Syringe pump

50 mL	20 min
100 mL	21 min
150 mL	31 min
250 mL	50 min

- Minimum infusion times of repeat dosing for 300 mg of casirivimab and 300 mg of imdevimab for IV infusion are:

Prefilled 0.9% NaCl or 5% dextrose infusion bag	Minimum infusion time
50 mL	20 min
100 mL	20 min
150 mL	30 min
250 mL	49 min

- Once infusion is complete, flush the tubing with 0.9% sodium chloride to ensure delivery of required dose.
- Observe for 1 h after infusion.

SC injection

- Administer the 4 syringes consecutively, each at different injection sites (thigh, back of the upper arm, or abdomen).
- *For post-exposure prophylaxis repeat dosing*: administer the 2 syringes consecutively, each at different injection sites (thigh, back of the upper arm, or abdomen).
- Do not inject into skin that is tender, damaged, bruised, or scarred.
- Observe for 1 h after injections.

administered to avoid underdosage.
- Once the infusion is complete, flush the tubing with 0.9% sodium chloride to ensure delivery of required dose.
- Observe for 1 h after infusion.

	• Administer the entire syringe via syringe pump over at least 16 min. • Once the infusion is complete, flush the tubing with 0.9% sodium chloride to ensure delivery of required dose. • Observe for 1 h after infusion.			
Dosage forms and strengths				
Product availability	*Cartons of 1 single-dose vial* • Bamlanivimab 700 mg/20 mL (35 mg/mL) (NDC 0002-7910-01) • Etesevimab: 700 mg/20 mL (35 mg/mL) (NDC 0002-7950-01)	*Carton of 1 co-formulated casirivimab and imdevimab vial* • Casirivimab 600 mg/10mL (60 mg/mL) and imdevimab 600 mg/mL (60mg/mL) (NDC 61755-039-01) *Cartons of 1 single-dose vial* • Casirivimab 1,332 mg/11.1 mL (120 mg/mL) (NDC 61755-024-01) • Casirivimab 300 mg/2.5 mL (120 mg/mL) (NDC 61755-026-01) • Imdevimab 1,332 mg/11.1 mL (120 mg/mL) (NDC 61755-025-01) • Imdevimab 300 mg/2.5 mL (120 mg/mL) (NDC 61755-027-01) *Carton of 2 single-dose vials; 1 of each antibody (NDC 61755-042-02)* • Casirivimab 1,332 mg/11.1 mL (120 mg/mL) (NDC 61755-024-00) • Imdevimab 1,332 mg/11.1 mL (120 mg/mL) (NDC 61755-025-00) *Carton of 2 single-dose vials; 1 of each antibody (NDC 61755-045-02)* • Casirivimab 300 mg/2.5 mL (120 mg/mL) (NDC 61755-026-00)	*Carton of 1 single-dose vial* • Sotrovimab 500 mg/8 mL (62.5 mg/mL) (NDC 0173-0901-86)	*Carton of 2 single-dose vials; 1 of each antibody (NDC 0310-7442-02)* • Tixagevimab 150 mg/1.5 mL (100 mg/mL) (NDC 0310-8895-01) • Cilgavimab 150 mg/1.5 mL (100 mg/mL) (NDC 0310-1061-01)

		• Imdevimab 300 mg/2.5 mL (120 mg/mL) (NDC 61755-027-00) *Dose Pack (may contain 2, 5, or 8 vials) provides 1,200 mg casirivimab and 1,200 mg of imdevimab* • 2 vials – 1 vial of casirivimab (1,332 mg) and 1 vial of imdevimab (1,332 mg) (NDC 61755-035-02) • 5 vials – 1 vial of casirivimab (1,332 mg) and 4 vials of imdevimab (300 mg) (NDC 61755-037-05) • 5 vials – 4 vials of casirivimab (300 mg) and 1 vial of imdevimab (1,332 mg) (NDC 61755-038-08) • 8 vials – 4 vials of casirivimab (300 mg) and 4 vials of imdevimab (300 mg) (NDC 61755-036-08)		
Product composition	Each 1 mL of bamlanivimab solution: • 35 mg of bamlanivimab • 0.4 mg L-histidine • 0.6 mg L-histidine hydrochloride monohydrate • 2.9 mg sodium chloride • 60 mg sucrose • 0.5 mg polysorbate 80	Each 2.5 mL of solution contains: • 300 mg of casirivimab or imdevimab • 1.9 mg L-histidine • 2.7 mg L-histidine monohydrochloride monohydrate • 2.5 mg polysorbate 80 • 200 mg sucrose Each 11.1 mL of solution contains: • 1,332 mg of casirivimab or imdevimab • 8.3 mg L-histidine • 12.1 mg L-histidine monohydrochloride monohydrate • 11.1 mg polysorbate 80 • 888 mg sucrose	Each 1 mL of sotrovimab solution: • 62.5 mg of sotrovimab • 1.51 mg L-histidine • 2.15 mg L-histidine monohydrochloride • 0.75 mg L-methionine • 0.4 mg polysorbate 80 • 70 mg sucrose	Each 1.5 mL of tixagevimab solution: • 150 mg of tixagevimab • 2.4 mg L-histidine • 3.0 mg L-histidine hydrochloride monohydrate • 0.6 mg polysorbate 80 • 123.2 mg sucrose
	Each 1 mL of etesevimab solution: • 35 mg of etesevimab • 1.55 mg L-histidine • 2.10 mg L-histidine hydrochloride monohydrate • 80.4 mg sucrose • 0.5 mg polysorbate 80			Each 1.5 mL of cilgavimab solution: • 150 mg cilgavimab • 2.4 mg L-histidine • 3.0 mg L-histidine hydrochloride monohydrate • 0.6 mg polysorbate 80 • 123.2 mg sucrose
Safety				
Contraindications	None	Previous severe hypersensitivity reactions, including anaphylaxis, to any component.		

Warnings and precautions	• Hypersensitivity including anaphylaxis and infusion-related reactions have been observed with administration of monoclonal antibodies. If an infusion-related reaction occurs, consider slowing or stopping the infusion and administering appropriate medications. • Clinical worsening of COVID-19 after administration has been reported and may include signs or symptoms of fever, hypoxia or increased respiratory difficulty, arrhythmia, fatigue and altered mental status. • Benefit of treatment has not been observed in patients hospitalized due to COVID-19. None of the monoclonal antibodies are authorized for use in inpatients.			• Hypersensitivity including anaphylaxis has been observed. If a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration, and initiate appropriate medications and/or supportive care. • Clinically significant bleeding disorders with intramuscular injection can occur and should be given in caution to individuals with thrombocytopenia or any coagulation disorder. • Cardiovascular events, including myocardial infarction and cardiac failure, were observed. A causal relationship has not been established but the risks and benefits should be considered in individuals at high risk for cardiovascular events.
Adverse reactions	Infusion reactions, nausea, pruritus, pyrexia	Infusion reactions, including pyrexia, chills, urticaria, pruritus, abdominal pain, and flushing	Infusion reactions, including pyrexia, chills, dizziness, dyspnea, pruritis, rash, and diarrhea	The most common adverse reactions (incidence ≥ 3%) are headache, fatigue, and cough.
Drug interactions	• Interaction studies have not been performed. • Not renally excreted or metabolized via CYP450 enzymes.			
Adverse event reporting	Report all serious adverse events or medication errors potentially related to the COVID-19 mAbs to the FDA MedWatch using the FDA Form 3500.			
Storage/stability				
Unopened vials	• Store at 2-8˚C • Do not freeze or shake • Protect from light • Bamlanivimab shelf-life extended to 18 mo (previously 12 mo)[f] • Etesevimab shelf-life extended to 18 mo (previously 12 mo)[g]	• Store at 2-8˚C • Do not freeze or shake • Protect from light • Unopened vials may be stored in the original carton at room temperature (up to 25˚C) and must be used within 30 days	• Store at 2-8˚C • Do not freeze or shake • Protect from light	• Store at 2-8˚C • Do not freeze or shake • Protect from light

Prepared infusion or injection	If not used immediately after dilution: • Stable at 2-8˚C for 24 h • Stable at room temperature (20-25˚C) for up to 7 h including infusion time	IV infusion – If not used immediately after dilution: • Stable at 2-8˚C for 36 h • Stable at room temperature (up to 25˚C) for up to 4 h SC injection – If not used immediately after preparation: • Stable at 2-8˚C for 4 h • Stable at room temperature (up to 25˚C) for up to 4 h • If refrigerated, allow syringes to equilibrate to room temperature for 20 min prior to administration	If not used immediately after dilution: • Stable at 2-8˚C for 24 h • Stable at room temperature (up to 25˚C) for up to 4 h	If not used immediately after preparation: • Stable at 2-8˚C for 4 h • Stable at room temperature (up to 25˚C) for up to 4 h
Availability				
How to order	Weekly distribution amounts for each state/territory will be determined by HHS based on weekly reports of new COVID-19 cases and hospitalizations in addition to data on inventories and use submitted by sites. State/Territorial Health Departments will determine where product goes in their jurisdictions.[h] Should you have any questions regarding this update in ordering and distribution procedures, please email the Federal COVID-19 Response Team at COVID19therapeutics@hhs.gov.			

COVID-19 monoclonal antibody: Evidence summary

Bamlanivimab (LY-Co555) plus etesevimab (LY-CoV016) clinical trials

- **Summary –** The clinical trial program of bamlanivimab (alone or in combination with etesevimab) consists of a phase 1 study of bamlanivimab in hospitalized patients (NCT04411628)[i], a phase 2/3 study in patients recently diagnosed with symptomatic COVID-19 in the ambulatory setting (BLAZE-1, NCT04427501)[j], and a phase 3 study in residents and long-term care facilities (BLAZE-2, NCT04497987)[k]. Additionally, bamlanivimab has been evaluated in the National Institute of Health (NIH) ACTIV-3 trial[l] (NCT04501978) and is currently being evaluated in the NIH ACTIV-2 trial[m] (NCT04518410). The bamlanivimab treatment arm of the ACTIV-3 trial was stopped early based on interim data demonstrating that bamlanivimab was unlikely to be effective in hospitalized patients who are in the late stage of their illness, suggesting that the timing of initiation of mAb therapy is critical to efficacy. The EUA for bamlanivimab *alone* has been revoked due to impaired efficacy with sustained prevalence of variants; however, bamlanivimab plus etesevimab is available via the EUA pathway.[n]
- **Dougan M, Nirula A, Azizad M, et al. *N Engl J Med*. 2021;385(15):1382-1392.**[j] Emergency use of bamlanivimab plus etesevimab for treatment of mild to moderate COVID-19 was authorized based on analysis of the phase 2/3 BLAZE-1 trial, a randomized, double-blind, placebo-controlled trial, in which outpatient (non-hospitalized) adults with mild-to-moderate COVID-19 infection (onset within 3 days of enrollment) were administered bamlanivimab plus etesevimab or placebo. The phase 3 clinical efficacy data included patients receiving bamlanivimab 700 mg and etesevimab 1,400 mg together, as well as patients receiving bamlanivimab 2,800 mg and etesevimab 2,800 mg. Among 1,035 high-risk patients, events – COVID-19 related hospitalizations or death – were significantly reduced in patients treated with the combination of bamlanivimab plus etesevimab compared with placebo (11 events (2.1%) vs. 36 events (7.0%), respectively; *P* = .0004). Ten COVID-19 related deaths occurred, all in the placebo group. Combination treatment also significantly reduced viral load and accelerated symptom improvement compared with placebo.
- **Press release March 2021.º** Lilly announced results of a new cohort of the BLAZE-1 trial evaluating bamlanivimab 700 mg plus etesevimab 1400 mg, which is the dosing now authorized in the EUA. According to the press release, among 769 high-risk patients, events – COVID-19 related hospitalizations or death – were reduced by 87% in patients treated with the combination of bamlanivimab 700 mg plus etesevimab 1400 mg compared with placebo (4 events (< 1%) vs. 15 events (6%), respectively; *P* < .0001). Four COVID-related deaths occurred, all in the placebo group. The safety profile of bamlanivimab plus etesevimab was consistent with prior data.

- **Cohen MS, Nirula A, Mulligan MJ, et al. *JAMA*. 2021;326(1):46-55.**[k] Emergency use of bamlanivimab plus etesevimab for post-exposure prophylaxis of COVID-19 was authorized based on analysis of the phase 3 BLAZE-2 trial, a randomized, double-blind, placebo-controlled trial, in which residents and staff of skilled nursing facilities, following a confirmed case of COVID-19 infection, were administered a single infusion of bamlanivimab 4,200 mg (n = 484) or placebo (n = 482). After 8 weeks of follow-up, there were 114 cases of symptomatic COVID-19 in the prevention population with a lower incidence in the bamlanivimab-treated group (8.5%) vs. placebo (15.2%) (odds ratio: 0.43; 95% CI, 0.28-0.68; *P* < .001). Four COVID-19 related deaths occurred in the prevention population; all in the placebo group.

Casirivimab (REGN10933) plus imdevimab (REGN10987) (REGEN-COV) clinical trials

- **Summary –** The clinical trial program of casirivimab and imdevimab consists of a phase 1/2/3 study in patients recently diagnosed with COVID-19 in the ambulatory setting (NCT04425629)[p], a phase 2/3 study in certain hospitalized patients with COVID-19 (NCT04426695)[q], and a phase 3 trial in healthy adults and adolescents who are household contacts of infected individuals (NCT04452318)[r]. Additionally, a UK-only trial (RECOVERY) evaluated casirivimab and imdevimab in hospitalized patients.[s]
- **Weinreich DM, Sivapalasingam S, Norton T, et al. *N Engl J Med*. Epub 2021.**[p] Emergency use of casirivimab and imdevimab for treatment of mild to moderate COVID-19 was based on the phase 3 component of the outpatient trial (NCT04425629), which compared the 1,200 mg and 2,400 mg dosage regimens of casirivimab and imdevimab to placebo. The casirivimab and imdevimab-treated group vs. placebo significantly reduced COVID-19 related hospitalization or death (7 events (1.0%) vs. 24 events (3.2%) and 18 events (1.3%) vs. 62 events (4.6%), respectively). Among the high-risk patients receiving the 1,200 mg dosage regimen (n = 736) vs. placebo (n = 748) there was 70% risk reduction in COVID-19 related hospitalization or death (*P* = .0024). There was a 71% risk reduction (*P* < .0001) among the high-risk patients receiving the 2,400 mg dosage regimen (n = 1,355) vs. placebo (n = 1,341). For both regimens compared with placebo, the median reduction of time to COVID-19 symptom resolution was 4 days (*P* < .0001).
- **O'Brien MP, Forleo-Neto E, Musser BJ, et al. *N Engl J Med*. 2021;385(13):1184-1195.**[r] Emergency use of casirivimab and imdevimab for post-exposure prophylaxis was based on the phase 3 component of the household contacts of infected individuals trial (NCT04452318), a randomized, double-blind, placebo-controlled trial. The trial enrolled participants without COVID-19 symptoms (asymptomatic) who lived in the same household as an individual who tested positive for SARS-CoV-2 within the 4 days prior and evaluated subcutaneous administration of casirivimab and imdevimab. Participants were tested for SARS-CoV-2 at baseline. Participants who tested negative were placed in the prevention trial (2069A). The 1,200 mg dosage regimen of casirivimab and imdevimab (n = 753) compared with placebo (n = 752) reduced the risk of symptomatic COVID-19 infection by 81% (*P* < .0001; 11 events (1.5%) vs. 59 events (7.8%), respectively) through day 29 in participants who tested negative for SARS-CoV-2 at baseline. For those who developed symptomatic COVID-19 infection, resolution of symptoms, on average, occurred after 1 week in the casirivimab and imdevimab group vs. 3 weeks in the placebo group. There was a 93% reduction in cumulative weeks with symptoms in the casirivimab and imdevimab group compared with placebo (13 weeks vs. 188 weeks, respectively; *P* < .0001).
- **Press release December 2020.**[t] Regeneron announced in a press release that the phase 2/3 trial evaluating casirivimab and imdevimab in hospitalized COVID-19 patients requiring low-flow oxygen who are seronegative for antibodies at baseline passed the futility analysis and will continue. In the futility analysis, seronegative patients treated with casirivimab and imdevimab had a lower risk of death or progressing to mechanical ventilation than patients treated with placebo (hazard ratio: 0.78; 95% CI, 0.51-1.2). Previously, the arm evaluating casirivimab and imdevimab in hospitalized COVID-19 patients requiring high-flow oxygen was stopped due to futility.
- **Horby PW, Mafham M, Peto L, et al. *medRxiv*. Epub 2021.**[s] The UK phase 3 RECOVERY (Randomised Evaluation of COVid-19 thERapY) trial, a randomized, controlled, open-label trial, in which hospitalized 9,785 patients with COVID-19 were randomized to receive usual care plus 8,000 mg casirivimab and imdevimab or usual care alone. Usual care was determined by the individual facilities and clinicians. The primary outcome was all-cause mortality at day 28. In seronegative patients (n = 3,153), 24% of patients in the casirivimab and imdevimab-treated group died vs. 30% in the usual care alone group (rate ratio: 0.80; 95% CI, 0.70-0.91; *P* = .001). The results were not statistically significant including the larger seropositive group.

Sotrovimab (VIR-7831) clinical trials

- **Summary –** The clinical trial program of sotrovimab consists of the ongoing phase 1/2/3 COMET-ICE trial[u] (NCT04545060), the ongoing phase 2 COMET-PEAK trial[v] (NCT04779879), the phase 3 COMET-TAIL trial[w], and the phase 3 COMET-STAR trial[w].
- **Gupta A, Gonzalez-Rojas Y, Juarez E, et al. *N Engl J Med*. 2021;385(21):1941-1950.[u]** Emergency use of sotrovimab was authorized based on the interim analysis of the phase 3 COMET-ICE trial, a randomized, double-blind, placebo-controlled trial, in which outpatient (non-hospitalized) adults with mild-to-moderate COVID-19 infection (onset within 5 days of enrollment) were administered sotrovimab 500 mg IV (n = 291) or placebo (n = 292). The primary endpoint was progression of COVID-19 at day 29, defined as hospitalization for > 24 hours for acute management of any illness or death from any cause. At day 29, 3 patients (1%) in the sotrovimab-treated group and 21 patients (7%) in the placebo group had progression of COVID-19 (adjusted relative risk reduction: 85%; 97.24% CI, 44-96; *P* = .002). At day 29, all-cause mortality was not seen in the sotrovimab-treated group vs. 1 patient in the placebo group. Analysis of change from baseline in viral load is not available as data are not yet available in the majority of the trial participants.
- **Press release June 2021.[w]** GlaxoSmithKline and Vir announced the final results of the phase 3 COMET-ICE trial. According to the press release, analysis of final day 29 data confirms sotrovimab significantly reduces hospitalization and risk of death in adults with mild-to-moderate COVID-19 at high risk for progression to severe disease. The primary endpoint was progression of COVID-19 at day 29, defined as hospitalization for > 24 hours for acute management of any illness or death from any cause. Of the 1,057 patients evaluated, at day 29, 6 patients (1%) in the sotrovimab-treated group and 30 (6%) in the placebo group had progression of COVID-19 (adjusted relative risk reduction: 79%; 95% CI, 50-91; *P* < .001). No deaths were observed in the sotrovimab-treated group compared with 2 (0.4%) in the placebo group.[c] Hospitalizations for > 24 hours were observed in 6 (1%) of the sotrovimab-treated groups compared with 29 (5%) in the placebo group (GSK Medical Affairs, email communication, January 11, 2022). In the safety analysis of 1,037 patients, the most common adverse events in the sotrovimab-treated group were rash (1%) and diarrhea (2%).

Tixagevimab (AZD8895) plus cilgavimab (AZD1061) (AZD7442) (Evusheld) clinical trials

- **Summary –** The clinical trial program of tixagevimab and cilgavimab consists of the ongoing phase 3 PROVENT trial[x] (NCT04625725) evaluating pre-exposure prophylaxis in patients who did not have a COVID-19 infection at baseline, the ongoing phase 3 TACKLE trial[y] (NCT04723394) evaluating outpatient treatment in patients with COVID-19 infection, and the ongoing phase 3 STORM CHASER trial[z] (NCT04625972) evaluating post-exposure prophylaxis of COVID-19. Additionally, tixagevimab and cilgavimab are being studied in the NIH ACTIV-3 trial (NCT04501978).[l]
- **Press release November 2021.[aa]** Emergency use of tixagevimab and cilgavimab was authorized based on results of the ongoing phase 3 PROVENT trial, a multicenter, randomized, double-blind, placebo-controlled trial, in which adult patients (≥18 years of age) at increased risk for inadequate immune response to vaccination or having an increased risk of COVID-19 infection were administered 300 mg of tixagevimab and cilgavimab (n = 3,460) or placebo (n = 1,737). The primary endpoint was the first case of SARS-CoV-2 RT-PCR positive symptomatic illness post dose prior to day 183. In the press release, at a median 6-month of patient follow-up, tixagevimab and cilgavimab reduced the risk of developing symptomatic COVID-19 compared with placebo by 83%. At the primary analysis, the reduction was reported to be 77% as compared with placebo. There were no cases of severe COVID-19 or COVID-19 related deaths in the tixagevimab and cilgavimab-treated group at either the primary analysis or the 6-month analysis.
- **Press release November 2021.[aa]** AstraZeneca announced exploratory analysis results of the phase 3 TACKLE trial, a multicenter, randomized, double-blind, placebo-controlled trial, in which non-hospitalized adult patients (≥ 18 years of age) with mild-to-moderate COVID-19 and symptomatic ≤ 7 days were administered 300 mg tixagevimab and cilgavimab (n = 452) or placebo (n = 451). The primary endpoint was the composite of either severe COVID-19 or death from any cause through day 29. In the press release, patients who had been symptomatic for ≤ 3 days, tixagevimab and cilgavimab reduced the risk of developing severe COVID-19 or death from any cause by 88% compared with placebo.
- **Press release June 2021.[bb]** AstraZeneca announced primary analysis results from the phase 3 STORM CHASER trial, a multicenter, randomized, double-blind, placebo-controlled trial, in which adult patients (≥ 18 years of age) within 8 days of a potential exposure to a laboratory-confirmed SARS-CoV-2 virus individual were administered 300 mg of tixagevimab and cilgavimab (n = 749) or placebo (n = 372). The primary endpoint was the first case of SARS-CoV-2 RT-PCR-positive symptomatic illness post dose to day 183. In the press release of the primary analysis of all patients, 3% of the tixagevimab and cilgavimab-treated group vs. 4.6% of the placebo group had a PCR-positive symptomatic illness. In the analysis of PCR-negative patients at baseline, 0.8% of the tixagevimab and cilgavimab-treated group vs. 3.1% of the placebo group had a PCR-positive symptomatic illness (relative risk reduction: 73%; 95% CI, 27-90).

Resistance

Summary – See the table below for summary of *in vitro* pseudotyped virus-like particle neutralization data for SARS-CoV-2.[a-d]

Variant	Bamlanivimab and Etesevimab	Casirivimab and Imdevimab	Sotrovimab	Tixagevimab and Cilgavimab
Alpha or B.1.1.7 (UK origin)	No change[a]	No change[b]	No change[a]	0.5- to 5.2-fold reduction in susceptibility
Beta or B.1.351 (South Africa origin)	431-fold reduction in susceptibility[c]	No change[b]	No change[a]	No change[a]
Gamma or P.1 (Brazil origin)	252-fold reduction in susceptibility[c]	No change[b]	No change[a]	No change[a]
Delta [+K417N] or B.1.617.2/AY.3 (India origin)	1,235-fold reduction in susceptibility[c]	No change[b]	No change[a]	No change[a]
Delta or AY.1/AY.2 (India origin)	No change[a]	No change[b]	No change[a]	No change[a]
Epsilon or B.1.427/B.1.429 (California origin)	9-fold reduction in susceptibility	No change[b]	No change[a]	No change[a]
Iota or B.1.526 (New York origin)	30-fold reduction in susceptibility	No change[b]	No change[a]	No change[a]
Kappa or B.1.617.1/B.1.617.3 (India origin)	6-fold reduction in susceptibility	No change[b]	No change[a]	No change[a]
Lambda or C.37 (Peru origin)	No change[a]	No change[b]	No change[a]	No change[a]
Mu or B.1.621/B.1.621.1 (Colombia origin)	116-fold reduction in susceptibility[c]	No change[b]	No change[a]	7.5-fold reduction in susceptibility
Omicron or B.1.1.529 (South Africa origin)	> 2,938-fold reduction in susceptibility[c]	> 1,013-fold reduction in susceptibility[d]	No change[a]	132- to 183-fold in reduction in susceptibility (12- to 30-fold reduction in susceptibility using authentic virus)

[a] < 5-fold reduction in susceptibility
[b] ≤ 2-fold reduction in susceptibility
[c] Bamlanivimab and etesevimab together are unlikely to be active against variants from this lineage
[d] Casirivimab and imdevimab together are unlikely to be active against variants from this lineage

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Vizient, Inc.
290 E. John Carpenter Freeway
Irving, TX 75062-5146
(800) 842-5146

To learn more, please contact
Kyle Hoelting at
kyle.hoelting@vizientinc.com.

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