Emergency Use Authorization (EUA) for bamlanivimab 700mg IV

Center for Drug Evaluation and Research (CDER) Memorandum on Fact Sheet Update

Identifying Information

Application Type (EUA or Pre-EUA) If EUA, designate whether pre-event or intra-event EUA request.	EUA
EUA Application Number(s)	90
Date of Memorandum	February 9, 2021
Sponsor (entity requesting EUA or pre-EUA consideration), point of contact, address, phone number, fax number, email address	Eli Lilly and Company: Christine Phillips, PhD, RAC Advisor, Global Regulatory Affairs - NA Mobile: (b) (6) Email: phillips_christine_ann@lilly.com
Manufacturer	Eli Lilly and Company
OND Division / Office	Division of Antivirals (DAV)/Office of Infectious Diseases (OID)
Integrated Review Completion Date	November 9, 2020
Proprietary Name	n/a
Established Name/Other names used during development	bamlanivimab (LY3819253, LY-CoV555)
Dosage Forms/Strengths	700 mg IV
Therapeutic Class	SARS-CoV-2 spike protein directed human IgG1κ monoclonal antibody (mAb)
Intended Use or Need for EUA	mild to moderate COVID-19
Intended Population(s)	treatment of mild to moderate COVID-19 illness in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older, who weigh at least 40 kg, and who are at high risk for

	progressing to severe COVID-19 illness and/or hospitalization

Emergency Use Authorization (EUA) 90 authorizes the emergency use of bamlanivimab for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. This memorandum provides a brief summary of the revisions being made to the Letter of Authorization (LOA) for EUA 90 and changes being made to the Fact Sheet for Healthcare Providers.

Under section 564(g) of the Federal Food, Drug & Cosmetic Act (FD&C Act), the Agency must periodically review the circumstances and appropriateness of an EUA. The Agency may revise an EUA, for example, if circumstances warrant revision to protect the public health or safety.

Based on the above, condition D in the Letter of Authorization for EUA 90 will be revised to state the following:

D. Lilly may request changes to this authorization, including to the authorized Fact Sheets for bamlanivimab. Any request for changes to this EUA must be submitted to the Office of Infectious Diseases/Office of New Drugs/Center for Drug Evaluation and Research. Such changes require appropriate authorization prior to implementation.[1]

The Letter of Authorization will also be revised to include two new conditions, which state the following:

E. Lilly may develop instructional and educational materials to facilitate the emergency use of the authorized bamlanivimab (e.g., materials providing information on product administration and/or patient monitoring) under condition D of this letter of authorization.

S. Healthcare facilities and providers will report therapeutics information and utilization data as directed by the U.S. Department of Health and Human Services.

[1] As per the memorandum from the FDA Commissioner of Food and Drugs entitled *Redelegations of Authority for Revisions to Emergency Use Authorizations (EUAs)*, dated December 22, 2020, the following types of revisions may be authorized without reissuing the letter of authorization: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to the letter of authorization; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study; (8) new strengths of the authorized product, new product sources (e.g., of active pharmaceutical ingredient) or of product components. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), (7), or (8), review and concurrence is required from the Counter-Terrorism and Emergency Coordination Staff/Office of the Center Director/CDER and the Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist.

Additional revisions to the Letter of authorization include the following:

- Non-substantive editorial revision to the authorized use statement;
- Revision to the requested statement to be included in adverse event reporting, as detailed in conditions E and P of the original authorization, to state: “bamlanivimab use for COVID-19 under Emergency Use Authorization (EUA)”;
- Revision to condition H of the original authorization to remove language that previously permitted the Lilly Indianapolis, IN facility to conduct the equivalent of third-party potency testing[2];
- Revision to condition I of the original authorization replacing “bacteriological or microscopic contamination” with “microbiological contamination”; and
- Revision to condition J of the original authorization to cross-reference condition D.

The Fact Sheet for Healthcare Providers will also be revised to include the addition of revision dates to the Recent Major Changes section, the correction of a typographical errors in Section 5, and the incorporation of new information on the mandatory reporting requirement now specified in condition S of the authorization. Lastly, a sentence was added to the antiviral resistance section of the Fact Sheet for Healthcare Providers to provide clarifying language regarding the activity of bamlanivimab against the UK variant.

Regulatory Conclusion:

Consistent with section 564(g) of the FD&C Act, FDA will be re-issuing the Letter of Authorization for EUA 90, dated November 9, 2020, in its entirety to include the revisions detailed above. FDA will also be authorizing a revised version of the Fact Sheet for Healthcare Providers as detailed above. These revisions, among other things, assist FDA in monitoring instructional and educational materials that are used to facilitate the emergency use of the authorized product and further assist the USG in making allocation decisions.

[2] Under the initial authorization, dated November 9, 2020, Eli Lilly was permitted to conduct the equivalent of third-party potency testing until February 1, 2021.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NATALIE M PICA
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WENDY W CARTER
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