CORRECTION OF DRUG INFORMATION

Subject: Refer only to the FDA Authorized Fact Sheet for bamlanivimab for preparation and administration instructions and disregard the document entitled “Bamlanivimab Alternative Preparation and Administration Information”.

Dear Health Care Provider:

You may have received a document entitled “Bamlanivimab Alternative Preparation and Administration Information,” which originated from Eli Lilly and Company, and was further distributed by the American Society of Health-System Pharmacists and potentially other sources. The information in that document should not be referred to because it contains information on the preparation and administration of bamlanivimab that differs from the currently authorized Fact Sheet.

Instead, Health Care Providers (HCPs) should prepare and administer bamlanivimab as detailed in the currently authorized HCP Fact Sheet available at:

- U.S. Food and Drug Administration (FDA) Emergency Use Authorization website

- Lilly’s bamlanivimab Emergency Use Authorization website
  http://www.bamlanivimab.com/, and click on the “Fact Sheet for Healthcare Providers”

This letter is being provided to you at the request of the U.S FDA.

**Bamlanivimab under Emergency Use Authorization**

The U.S. FDA has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product bamlanivimab for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

**LIMITATIONS OF AUTHORIZED USE**

- Bamlanivimab is not authorized for use in patients:
  - 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 with bamlanivimab has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

Possible side effects of bamlanivimab include: anaphylaxis and infusion-related reactions, nausea, diarrhea, dizziness, headache, itching and vomiting.

Bamlanivimab is authorized, but not approved, for these uses for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the bamlanivimab under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

**Reporting Adverse Events**
Per the requirements for bamlanivimab administration under the EUA, healthcare providers are responsible for mandatory reporting of all medication errors and serious adverse events potentially related to bamlanivimab treatment. Refer to the Fact Sheet and other resources above for detailed instructions.

You may also contact Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921) or visit [http://www.bamlanivimab.com/](http://www.bamlanivimab.com/) if you have questions about the safe and effective use of bamlanivimab or requirements associated with its use under the EUA.

Sincerely,

Bradley Woodward, MD
Vice President, Global Patient Safety
Eli Lilly and Company