## IMPORTANT PRESCRIBING INFORMATION

Subject: Revocation Of Emergency Use Authorization 90,
Bamlanivimab Alone For the Treatment of Mild to Moderate
COVID-19

## Dear Healthcare Provider:

In response to a request from Eli Lilly and Company, the U.S. Food and Drug Administration (FDA) has revoked the Emergency Use Authorization (EUA) of bamlanivimab alone for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) (EUA 90). Lilly made this request because there is now adequate supply of etesevimab for administration with bamlanivimab, and the combination neutralizes more of the emerging COVID-19 variants in the U.S. than bamlanivimab alone.

As a result, bamlanivimab alone is no longer authorized for use in the U.S., given the availability of authorized monoclonal antibody combinations.

Importantly, revocation of the bamlanivimab alone (EUA 90) is not due to any new safety concerns.

Lilly has removed information on the use of bamlanivimab alone from the U.S. website, medical education materials, and other references.

Bamlanivimab remains available in the U.S. for use together with etesevimab under EUA 94. If you have bamlanivimab at your facility, please do not dispose of it as it can be used together with etesevimab under EUA 94. Adequate supply of etesevimab is available for administration with bamlanivimab. Information on how to order etesevimab is available on <a href="LillyAntibody.com"><u>LillyAntibody.com</u></a> or by calling 1-855-LillyC19 (1-855-545-5921).

The FDA issued EUA 94 for emergency use of bamlanivimab and etesevimab administered together for the treatment of mild to moderate 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. The administration of bamlanivimab and etesevimab together is an important option for patients during the COVID-19 pandemic.

Healthcare providers should direct questions about bamlanivimab and etesevimab to Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921). Additional information on the use of bamlanivimab and etesevimab together, including the authorized Bamlanivimab and Etesevimab Fact Sheet for Health Care Providers, can be found at www.BAMandETE.com.

## Reporting Adverse Events:

Per the requirements for bamlanivimab and etesevimab administration under the EUA, healthcare providers are responsible for mandatory reporting of all medication errors and serious adverse events potentially related to bamlanivimab and etesevimab treatment. Refer to the Fact Sheet and <a href="https://www.BAMandETE.com">www.BAMandETE.com</a> for detailed instructions.

Sincerely,

ELI LILLY AND COMPANY

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Eli Lilly and Company