Health Advisory:

National Pause for the Distribution and Utilization of Bamlanivimab and Etesevimab for the Treatment of Mild to Moderate COVID-19

06.30.2021

This document will be updated as new information becomes available. The current version can always be viewed at http://www.health.mo.gov.

The Missouri Department of Health and Senior Services (DHSS) is now using four types of documents to provide important information to medical and public health professionals, and to other interested persons.

Health Alerts convey information of the highest level of importance which warrants immediate action or attention from Missouri health providers, emergency responders, public health agencies, and/or the public.

Health Advisories provide important information for a specific incident or situation, including that impacting neighboring states; may not require immediate action.

Health Guidances contain comprehensive information pertaining to a particular disease or condition, and include recommendations, guidelines, etc. endorsed by DHSS.

Health Updates provide new or updated information on an incident or situation; can also provide information to update a previously sent Health Alert, Health Advisory, or Health Guidance; unlikely to require immediate action.

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FROM: **Robert Knodell, DHSS Acting Director**

SUBJECT: **National Pause for the Distribution and Utilization of Bamlanivimab and Etesevimab for the Treatment of Mild to Moderate COVID-19**

The Missouri Department of Health and Senior Services (DHSS) received important prescribing information from Eli Lilly, manufacturer of bamlanivimab and etesevimab. Content of Lilly's notification is repeated below and can also be found at https://www.covid19.lilly.com/assets/pdf/bam-ete/bam-ete-pause.pdf

The Assistant Secretary for Preparedness and Response and the Food and Drug Administration (FDA) have paused the distribution of bamlanivimab and etesevimab across all 50 states within the United States effective 25 June 2021 due to reduced effectiveness against certain specific viral variants. As a result, do not use bamlanivimab and etesevimab administered together at this time. Use other authorized monoclonal antibodies to treat patients with mild to moderate COVID-19. Importantly, the pause of bamlanivimab and etesevimab distribution and use is not due to any new safety concerns.

The Centers for Disease Control and Prevention has identified that the combined frequencies of the P.1 (Gamma) variant (first identified in Brazil) and the B.1.351 (Beta) variant (first identified in South Africa) throughout the United States now exceeds 11% and is trending upward (https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html). Results from in vitro assays that are used to assess the susceptibility of viral variants to particular monoclonal antibodies suggest that bamlanivimab and etesevimab administered together are not active against either the P.1 (Gamma) or B.1.351 (Beta) variants. These assays use "pseudotyped-virus-like particles" that help determine likely susceptibility of the live SARS-CoV-2 variant viruses.

The duration of this pause will be determined in close coordination with the FDA and US government. If you have bamlanivimab and etesevimab at your facility, you do not need to dispose of these drugs at this time.

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 Healthcare Providers, can be found at www.BAMandETE.com.

Reporting Adverse Events:

Per the requirements for bamlanivimab and etesevimab administration under the Emergency Use Authorization (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 www.BAMandETE.com for detailed instructions.

Missouri healthcare providers and public health practitioners: Please contact your local public health agency or the Missouri Department of Health and Senior Services' (DHSS') Bureau of Communicable Disease Control and Prevention at 573-751-6113 or 800-392-0272 (24/7) with questions regarding this health advisory.