From: ASPRStakeHolderNoReply (OS/ASPR) <ASPRStakeHolderNoReply@hhs.gov>
Sent: Thursday, September 2, 2021 4:10 PM
To: ASPR Stake Holder (OS/ASPR) <ASPRStakeholder@hhs.gov>
Cc: COVID19-Therapeutics (OS/ASPR) <COVID19.Therapeutics@hhs.gov>
Subject: Pause in distribution of bam/ete lifted for all jurisdictions

Dear Stakeholder,

The Assistant Secretary for Preparedness and Response (ASPR) and the Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services are committed to ensuring timely and transparent communication regarding the COVID-19 monoclonal antibody treatments currently authorized for emergency use in certain patients with COVID-19.

On August 27, 2021, we informed you of revisions to the authorized use of bamlanivimab and etesevimab administered together under Emergency Use Authorization (EUA) 094. The EUA was revised to authorize the use of bamlanivimab and etesevimab, administered together, only in states, territories, and US jurisdictions in which recent data shows the combined frequency of variants resistant to bamlanivimab and etesevimab administered together is less than or equal to 5%.

Based on FDA's evaluation of the most recently available SARS-CoV-2 variant frequency data, we are informing you today that bamlanivimab and etesevimab, administered together, can be used in all U.S. states, territories, and jurisdictions under the conditions of authorization for EUA 94. ASPR will resume the distribution of bamlanivimab and etesevimab together and etesevimab alone (to pair with existing supply of bamlanivimab at a facility for use under EUA 094) to all U.S. states, territories, and jurisdictions.

Since June 2021, there has been a sustained increase in the circulation of the Delta variant (B.1.617.2). Based on in vitro assays that are used to assess the susceptibility of viral variants to monoclonal antibodies, bamlanivimab and etesevimab, administered together, **are** expected to retain activity against the Delta variant (B.1.617.2), which is now the dominant variant in the United States. The increase in prevalence of Delta has been associated with a decrease at the same time in the frequency of identified variants that are expected to be resistant to bamlanivimab and etesevimab.

ASPR and FDA will continue to work with the CDC and the National Institutes of Health on surveillance of variants that may impact the use of the monoclonal antibody therapies authorized for emergency use. We will provide further updates and consider additional action as new information becomes available.

Should you have any questions or concerns, please email COVID19Therapeutics@hhs.gov.

Regards,
The Federal COVID-19 Response Team