Breaking News: National Pause on Distribution of Certain Monoclonal Antibody Therapeutics

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The Assistant Secretary for Preparedness and Response (ASPR) and Food and Drug Administration (FDA) announced today that ASPR is immediately pausing all distribution of bamlanivimab and etesevimab together and etesevimab alone (to pair with existing supply of bamlanivimab at a facility for use under emergency use authorization (EUA)) on a national basis until further notice due to the growing presence of COVID-19 variants with reduced susceptibility to these therapies.

According to the Centers for Disease Control and Prevention (CDC), the combined frequencies of the SARS-CoV-2 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 exceed 11% and are trending upward. 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 or B.1.351 variants.

The FDA recommends that healthcare providers instead use the alternative authorized monoclonal antibody therapies, REGEN-COV and sotrovimab. Based on similar in vitro assay data currently available, REGEN-COV and sotrovimab are likely to retain activity against the P.1 or B.1.351 variants.

All treatment delivery sites can continue ordering REGEN-COV from the authorized distributor by following the existing ordering and reporting procedures. Sotrovimab is not distributed by the federal government. Treatment sites may find information on the availability and ordering of sotrovimab by visiting GlaxoSmithKline's website.

Healthcare providers should review the Antiviral Resistance information in Section 15 of the authorized Fact Sheets for each monoclonal antibody therapy available under an EUA for details regarding specific variants and resistance. Healthcare providers may also refer to the CDC website and information from state and local health authorities regarding reports of viral variants of importance in their region to guide treatment decisions.

ASHP will continue to update members as new information becomes available.