bamlanivimab – Emergency use authorization revoked

- On April 16, 2021, the FDA revoked the emergency use authorization (EUA) for Eli Lilly's bamlanivimab, *when administered alone*, to be used for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and certain pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 vial testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.
    - In the U.S., bamlanivimab alone should no longer be administered. However, sites of care should not dispose of bamlanivimab supply; instead, they should order etesevimab to pair with it.
- Eli Lilly requested the FDA revoke the EUA for bamlanivimab 700 mg alone. Lilly made this request due to the evolving variant landscape in the U.S. and the full availability of bamlanivimab/etesevimab together.
    - This request is not due to any new safety concern.
- Recent data from the U.S. Centers for Disease Control and Prevention's (CDC) national genomic surveillance program show an increased frequency of SARS-CoV-2 variants that are expected to be resistant to bamlanivimab administered alone.
    - As of mid-March 2021, approximately 20% of viruses sequenced in the U.S. were reported as variants expected to be resistant to bamlanivimab alone, increasing from approximately 5% in mid-January 2021.
- Additionally, there are currently no testing technologies available that enable health care providers to test individual patients for SARS-CoV-2 viral variants prior to start of treatment with monoclonal antibodies. Therefore, empiric treatment with monoclonal antibody therapies that are expected to work broadly against variants across the nation should be used to reduce the likelihood of treatment failure.
- Alternative monoclonal antibody therapies remain available under EUA, including REGN-COV (casirivimab/imdevimab) and bamlanivimab/etesevimab, for the same uses as previously authorized for bamlanivimab alone.
    - The FDA believes that these alternative monoclonal antibody therapies remain appropriate to treat patients with COVID-19 when used in accordance with the authorized labeling based on information available at this time.