

## **Frequently Asked Questions on the Revocation of the Emergency Use Authorization for Bamlanivimab Administered Alone (EUA 90)**

### **Q. Why was the Emergency Use Authorization (EUA) for bamlanivimab administered alone (EUA 90) revoked?**

A. FDA is required to regularly review the circumstances and appropriateness of an Emergency Use Authorization (EUA), including review of emerging scientific data associated with the emergency use of an authorized product. Since the initial authorization of bamlanivimab administered alone for emergency use on November 9, 2020, there has been a sustained increase in SARS-CoV-2 viral variants across the U.S. that are resistant to bamlanivimab alone. Given the frequency of these particular viral variants, and since current testing technologies are not available to ascertain whether a particular patient who has tested positive for coronavirus disease 2019 (COVID-19) is infected with a viral variant prior to initiation of treatment, there is an increased risk of treatment failure when bamlanivimab is administered alone. As such, based on the totality of scientific evidence available, the Agency has concluded that the known and potential benefits of bamlanivimab administered alone no longer outweigh the known and potential risks for the product. Therefore, the Agency has determined that the criteria for issuance of an EUA are no longer met and has revoked EUA 90 for bamlanivimab administered alone for the treatment of COVID-19.

For more information, please see the [Letter of Revocation](#).

### **Q. Was the EUA for bamlanivimab alone revoked due to a safety issue?**

A. No. The revocation is not due to a safety issue.

### **Q. Can health care facilities use their current supplies of bamlanivimab?**

A. With the revocation of EUA 90, healthcare facilities and providers may *only* administer bamlanivimab together with etesevimab consistent with the terms and conditions of the EUA for [bamlanivimab and etesevimab administered together \(EUA 94\)](#). With the revocation of EUA 90, bamlanivimab administered alone is no longer authorized for emergency use. Sites intending to use an existing supply of bamlanivimab must order a sufficient supply of etesevimab to pair with the supply of bamlanivimab on hand.

### **Q. If a health care facility has excess supply of bamlanivimab alone, what should the facility do with the excess supply?**

A. Health care facilities with excess supply of bamlanivimab that cannot be paired with etesevimab are asked to continue to store this supply pending further recommendations from the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR).

### **Q. Why did FDA issue the EUA for bamlanivimab alone for the treatment of COVID-19 initially?**

A. On November 9, 2020, FDA issued an Emergency Use Authorization (EUA) for the use of bamlanivimab alone 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 directly SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization). FDA's issuance of the EUA for bamlanivimab alone reflected its determination that the statutory criteria under section 564(c) of the Federal Food, Drug & Cosmetic Act [were satisfied](#).

At the time of authorization, treatment with bamlanivimab alone was appropriate based on the totality of scientific information available to the Agency.

**Q. Should patients be concerned if they were given bamlanivimab alone to treat COVID-19?**

A. No. The revocation of the EUA for bamlanivimab alone is not due to safety concerns, and FDA is not aware of any patients having issues of concern associated with the use of bamlanivimab. Patients should contact their health care provider with any questions.

**Q. Is FDA monitoring the SARS-CoV-2 viral variants and their potential impact on other authorized monoclonal antibody treatments?**

A. Yes. FDA regularly reviews the circumstances and appropriateness of each EUA. As part of FDA's review of the authorized monoclonal antibody therapies, the Agency continues to closely monitor and continually assess the impact of viral variants on authorized products and is working with medical product sponsors to provide information on evaluating any potential impact that the circulating viral variants may have on the activity of their products.

**Q. Why is the FDA not revoking other monoclonal antibody treatment emergency use authorizations?**

A. Based on the scientific information currently available, FDA believes that the authorized monoclonal antibody therapies, including [REGEN-COV \(casirivimab and imdevimab, administered together\)](#), and [bamlanivimab and etesevimab administered together](#), continue to meet the statutory criteria supporting their issuance to treat patients with COVID-19 when used in accordance with the authorized labeling.