Fact Sheet for Patients, Parents and Caregivers
Emergency Use Authorization (EUA) of Bamlanivimab and Etesevimab for Coronavirus Disease 2019 (COVID-19)

You or your child are being given two medicines together called **bamlanivimab and etesevimab** for the treatment or post-exposure prophylaxis for prevention of coronavirus disease 2019 (COVID-19). SARS-CoV-2 is the virus that causes COVID-19. This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking bamlanivimab and etesevimab.

Receiving bamlanivimab and etesevimab may help to treat COVID-19 in certain people, or help to prevent COVID-19 in certain people who have been exposed to someone infected with SARS-CoV-2 and who are at high risk of an exposure because of being in the same setting, such as nursing homes or prisons.

Read this Fact Sheet for information about bamlanivimab and etesevimab. Talk to your or your child's healthcare provider if you have questions. It is your choice if you or your child receive bamlanivimab and etesevimab or you may stop them at any time.

What is COVID-19?
COVID-19 is caused by a virus called a coronavirus, SARS-CoV-2. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your or your child's underlying medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, and other conditions, including obesity, seem to be at higher risk of being hospitalized for COVID-19. Older age, with or without other conditions, also places people at higher risk of being hospitalized for COVID-19.

What are the symptoms of COVID-19?
The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause other medical conditions to become worse.

What are bamlanivimab and etesevimab?
Bamlanivimab and etesevimab are investigational medicines used together in adults and children who are at high risk for developing severe COVID-19, including hospitalization or death for:

- **treatment** of mild to moderate symptoms of COVID-19, OR
- **post-exposure prophylaxis for prevention** of COVID-19 in persons who are:
  - not fully vaccinated against COVID-19 (Individuals are considered to be fully vaccinated 2 weeks after the second dose in a 2-dose series [such as the Pfizer or Moderna vaccines], or 2 weeks after a single-dose dose vaccine [such as Johnson & Johnson's Janssen vaccine]), **or**
  - are not expected to build up enough of an immune response to the complete COVID-19 vaccination (for example, someone with immunocompromising conditions, including someone who is taking immunosuppressive medications), **and**
    - have been exposed to someone who is infected with SARS-CoV-2. Close contact with someone who is infected with SARS-CoV-2 is defined as being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). For additional details, go to https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html, **or**

- someone who is at high risk of being exposed to someone who is infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons).

Bamlanivimab and etesevimab are investigational because they are still being studied. There is limited information known about the safety or effectiveness of using bamlanivimab and etesevimab to treatment or prevention of COVID-19. Bamlanivimab and etesevimab are not authorized for pre-exposure prophylaxis for prevention of COVID-19.

The FDA has authorized the emergency use of bamlanivimab and etesevimab together for the treatment of COVID-19 and the post-exposure prophylaxis for prevention of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the section "**What is an Emergency Use Authorization (EUA)?**" at the end of this Fact Sheet.

What should I tell the healthcare provider before I or my child receive bamlanivimab and etesevimab?
Tell the healthcare provider about all of your or your child's medical conditions, including:

- Having any allergies
- Having received a COVID-19 vaccine
- Having any serious illnesses
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

How are bamlanivimab and etesevimab given?

- Bamlanivimab and etesevimab are given one time through a vein (intravenous or IV).
- One dose of bamlanivimab and etesevimab will be given by IV infusion. The infusion will take 16 – 60 minutes or longer. Your or your child's healthcare provider will determine the duration of the infusion.

What are the important possible side effects of bamlanivimab and etesevimab?

Possible side effects of bamlanivimab and etesevimab:

- Allergic reactions. Allergic reactions can happen during and after infusion with bamlanivimab and etesevimab. Tell your or your child's healthcare provider right away if any of the following signs and symptoms of allergic reactions occur: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of the lips, face, or throat, rash including hives, itching, muscle aches, feeling faint, dizziness, and sweating. These reactions may be severe or life threatening.
- Worsening of COVID-19 symptoms after bamlanivimab and etesevimab therapy for active infection: You or your child may experience new or worsening symptoms after infusion for mild to moderate COVID-19, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these occur, contact your or your child's healthcare provider or seek immediate medical attention as some of these events have required hospitalization. It is unknown if these events are related to treatment or are due to the progression of COVID-19.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

These are not all the possible side effects of bamlanivimab and etesevimab. Not a lot of people have been given bamlanivimab and etesevimab. Serious and unexpected side effects may happen. Bamlanivimab and etesevimab are still being studied so it is possible that all of the risks are not known at this time.

It is possible that bamlanivimab and etesevimab could interfere with your or your child's body's own ability to fight off a future infection of SARS-CoV-2. Similarly, bamlanivimab and etesevimab may reduce the body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your or your child's healthcare provider if you have any questions.

What other treatment choices are there?
Like bamlanivimab and etesevimab, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for information on the emergency use of other medicines that are not approved by FDA to treat people with COVID-19. Your or your child's healthcare provider may talk with you about clinical trials you or your child may be eligible for.

It is your choice whether you or your child should be treated or not to be treated with bamlanivimab and etesevimab. Should you decide that you or your child should not receive bamlanivimab and etesevimab or stop it at any time, it will not change your or your child's standard medical care.

What other prevention choices are there?
Vaccines to prevent COVID-19 are approved or available under Emergency Use Authorization. Use of bamlanivimab and etesevimab does not replace vaccination against COVID-19.

Like bamlanivimab and etesevimab, FDA may allow for the emergency use of other medicines for post-exposure prophylaxis for prevention of COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for information on the emergency use of other medicines that are not approved by FDA for post-exposure prophylaxis for prevention of COVID-19. The healthcare provider may talk with you about clinical trials you or your child may be eligible for.

Bamlanivimab and etesevimab are not authorized for pre-exposure prophylaxis for prevention of COVID-19.

What if I am pregnant or breastfeeding?
There is limited experience treating pregnant women or breastfeeding mothers with bamlanivimab and etesevimab. For a mother and unborn baby, the benefit of receiving bamlanivimab and etesevimab may be greater than the risk from the treatment. If pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects with bamlanivimab and etesevimab?
Tell the healthcare provider right away if you or your child have any side effect that bothers you or your child, or does not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch, call 1-800-FDA-1088, or contact Eli Lilly and Company at 1-855-LILLY19 (1-855-545-5921).

How can I learn more?
- Ask your or your child's healthcare provider
- Visit www.COVIDAntibody.com
- Visit https://www.covidtreatmentguidelines.nih.gov/
- Contact your local or state public health department

What is an Emergency Use Authorization (EUA)?
The United States FDA has made bamlanivimab and etesevimab available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

Bamlanivimab and etesevimab have not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA must determine, among other things, that based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate,

approved and available alternatives. All of these criteria must be met to allow for the medicine to be used in the treatment of COVID-19 or prevention of COVID-19 during the COVID-19 pandemic.

The EUA for bamlanivimab and etesevimab together is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

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