What is bamlanivimab?
Bamlanivimab is an investigational medicine used for the treatment of COVID-19 in non-hospitalized adults and adolescents 12 years of age and older. Bamlanivimab is investigational because it is still being studied. There is limited information known about the safety or effectiveness of using bamlanivimab to treat people with COVID-19.

The FDA has authorized the emergency use of bamlanivimab for the treatment of COVID-19 under an Emergency Use Authorization (EUA). See the section “What is an Emergency Use Authorization (EUA)” at the end of this fact sheet.

Who is this drug for?
Bamlanivimab is a treatment option for people with COVID-19 who:

- Are 12 years of age or older and weigh at least 88 pounds
- Have mild to moderate symptoms for 7 days or less
- Are at high risk to get very sick from COVID-19

This drug is not for people who are already in the hospital because of their COVID-19 symptoms.

Am I at high risk?
For adults, bamlanivimab may be an option if you:

- Are age 65 or older
- Have obesity, with a body mass index (BMI) of 35 or higher
- Have diabetes, chronic kidney disease, or a condition that weakens the immune system, or take a medication that weakens the immune system
- Are age 55 or older and have heart disease, high blood pressure or lung disease

For pediatric patients age 12–17, bamlanivimab may be an option if you:

- Have obesity, with a BMI higher than 85 percent of patients your same age and gender
- Have heart disease, sickle cell disease, or long-term lung disease
- Have a developmental condition like cerebral palsy
- Regularly use medical technology, like a ventilator or feeding tube

How does the medicine work?
Bamlanivimab is a neutralizing antibody medicine. This means that it contains man-made antibodies that are similar to the antibodies of patients who have recovered from COVID-19. These antibodies may help limit the amount of COVID-19 virus in your body which could give your body more time to learn how to make its own antibodies.

How will I take the medicine?
Bamlanivimab is given to you through a vein (intravenous or IV) for at least 1 hour. You will receive one dose of this medicine. After the infusion, you will need to stay for 1 more hour to make sure you are feeling okay to go home.
What are the side effects?
Side effects can range from mild to serious and may include:

- Wheezing or trouble breathing
- Swollen lips, face or throat
- Flu-like symptoms (fever, sweating, chills, cough, sore throat, headache or muscle pain)
- Upset stomach (nausea, vomiting or diarrhea)
- Itching, swelling, rash or hives
- Dizziness or low blood pressure
- Changes in your heartbeat

Tell your doctor or nurse right away if you have any side effects during or after your infusion.

Keep in mind that only a limited number of people have taken bamlanivimab – scientists are still learning about its side effects and risks. Serious and unexpected side effects may occur.

What if I am pregnant or breast feeding?
Bamlanivimab has not been used on many pregnant or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving bamlanivimab may be greater than the risk from treatment. If you are pregnant or breastfeeding, discuss with your health care provider.

How can I get ready for my appointment?
Plan for the infusion appointment to take about 3-4 hours. Most people will go home the same day, unless they have a serious side effect from the infusion.

Before the appointment, make sure to get good night’s sleep, drink plenty of water, and eat a light meal. Wear warm, comfortable clothes, including a shirt with sleeves you can roll up over your elbows. It’s also important to wear a mask to prevent the spread of COVID-19.

When the clinic calls to make your appointment, you will be told where to go and what precautions you will take to prevent the spread of COVID-19.

What happens after my appointment?
Continue to quarantine per the instructions given when you were tested for COVID-19. If your COVID-19 symptoms worsen, contact your primary care doctor or seek medical attention.

Tell your health care provider right away if you have side effects or new symptoms that bother you or don’t go away.

If you have any side effects, you may report these to FDA MedWatch at www.fda.gov/medwatch or by calling 1-800-FDA-1088.

What is an Emergency Use Authorization (EUA)?
The United States FDA has made bamlanivimab available under an emergency access mechanism called an Emergency Use Authorization (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 has not undergone the same type of review as an FDA-approved or cleared product. The FDA may issue an EUA when certain criteria are met, which include that there are no adequate, approved and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance and labeling, and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

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

How can I learn more?
Visit www.bamlanivimab.com or www.covid19treatmentguidelines.nih.gov. You may also contact your health care provider for more information.