**Bamlanivimab Informed Consent Sample Form**



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***This form should be accompanied by the current “Fact Sheet for Patients, Parents, and Caregivers, Emergency Use Authorization (EUA) of Bamlanivimab for Coronavirus Disease 2019 (COVID-19).”***

Patient Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_

Bamlanivimab is an investigational drug used to treat COVID-19. COVID-19 is caused by a virus called a coronavirus. There is no proven treatment for this possibly serious condition. The Bamlanivimab “Fact Sheet for Patients, Parents and Caregivers” provides details about the drug, potential risks, and potential benefits of taking the drug.

**Information about Bamlanivimab**

Bamlanivimab is an investigational drug that is not yet approved by the Food and Drug Administration (FDA). However, the FDA has given an Emergency Use Authorization (EUA) for its use on a limited basis. This is not the same as FDA approval.

The drug is used for patients who have not been admitted to the hospital but are at high risk for getting more severe COVID-19 symptoms, which could lead to being admitted to the hospital.

If this drug is ordered to be given, it is because the person meets the guidelines for high risk. The one dose of the drug will be given through a vein.

**Expected Results of Bamlanivimab**

Bamlanivimab is designed to mimic the immune system’s ability to fight off harmful viruses like COVID-19. It is directed against the spike protein of SARS-CoV-2 and is designed to block the virus’ attachment and entry into human cells.

Taking the drug could result in Covid-19 symptoms not getting worse, to a point where hospital care is not needed. Early drug studies show that people taking Bamlanivimab were less likely to go to the Emergency Department (ED) or be admitted to the hospital.

**Possible Other Forms of Treatment**

At this time there are no other adequate, approved, and available treatments to Bamlanivimab for the treatment of mild-to-moderate COVID-19. You still have a choice to take or refuse the drug. This will not change your standard medical care.

**Serious Possible Risks, Complications, and Expected Benefits**

Possible side effects may include allergic and infusion site reactions. Allergic reactions may include fever, chills, nausea, headache, shortness of breath, low blood pressure, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, and dizziness. Side effects of receiving a drug through a vein include brief pain, bleeding, skin bruising, soreness, swelling and possible infection at the site. The drug is still being studied, so it is possible that all of the risks and side effects from using the drug to treat COVID-19 are not known at this time.

When used under the conditions described by the drug maker, the known and potential benefits of Bamlanivimab outweigh its known and potential risks.

**Patient Consent**

**I have been given and have read, or had read to me the “Fact Sheet for Patients, Parents and Caregivers” regarding important information about Bamlanivimab.** I understand that no promise has been made to me about whether Bamlanivimab can stop Covid-19 symptoms from getting worse. I was given the chance to talk to my doctor about my condition and treatment. All my questions have been answered to my satisfaction.

Knowing the facts and risks, I am choosing to move forward with getting Bamlanivimab for the treatment of mild to moderate COVID-19.

Provider Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_ Time: \_\_\_\_\_\_

Patient or Legal Representative Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_ Time: \_\_\_\_\_

Representative’s Relationship to Patient: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_