MORRIS HOSPITAL
& HEALTHCARE CENTERS
150 West High Street
Morris, IL 60450
www.morrishospital.org
People You Know. Extraordinary Care.

CONSENT FOR EMERGENCY USE OF AN FDA INVESTIGATIONAL AGENT

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1. INFORMATION ABOUT AUTHORIZED EMERGENCY TREATMENTS

We have determined that you have a COVID-19 infection which is a life-threatening disease. Bamlanivimab and etesevimab may help you. **While this treatment may be helpful, no currently used medication treatments are likely to prolong your life or cure a COVID-19 infection.**

Bamlanivimab and etesevimab is an investigational agent. An investigational agent is one that researchers are still studying to find out whether it's safe and effective. **Because bamlanivimab and etesevimab is investigational, the Food and Drug Administration (FDA) has not yet approved it for general use; however, the FDA has authorized emergency use of the drug for use in cases of COVID-19 infection under 21 U.S.C. 360bbb-3 of the Food, Drug, and Administration Act (also explained in the attached FDA letter regarding bamlanivimab and etesevimab).**

Before you sign this form, be sure you understand how bamlanivimab and etesevimab relates to your condition, as well as the risks and possible benefits of using it.

2. SPECIFIC INFORMATION ABOUT THE TREATMENT

2.1 Why is this bamlanivimab and etesevimab being recommended?
Bamlanivimab and etesevimab is a monoclonal antibody used to treat COVID-19 infections in non-hospitalized patients with mild to moderate symptoms who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization.

2.2 What can I expect when I receive this treatment?
You will receive this medication in an outpatient setting. An IV will be started. The medication will be prepared specifically for you in the pharmacy department. The infusion will take approximately one hour, during which time you will be closely monitored. After the infusion is complete, you will continue to be monitored for a minimum of one hour.

3. COSTS ASSOCIATED WITH THIS TREATMENT

3.1 You or your insurance company will be responsible for the costs related to this treatment, including the cost of treatment if the bamlanivimab and etesevimab makes you sick or causes you injury. You will be responsible for any costs your insurance does not cover. Please note that your insurance is not obligated to pay for any care or treatments consequent to the use of bamlanivimab and etesevimab, unless it is specifically required to do so by law or contract. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company.

3.2 By signing this form, you do not give up your right to seek payment if you are harmed as a result of receiving this treatment.

4. HOW INFORMATION ABOUT YOU WILL BE SHARED

4.1 If you give us permission to use bamlanivimab and etesevimab, we will give the following information about you to Eli Lilly and Company (the manufacturer or supplier of bamlanivimab and etesevimab) and may provide the same to the Institutional Review Board of Morris Hospital (IRB):

- Any problems that occur when you are treated with this bamlanivimab and etesevimab.

4.2 Morris Hospital & Healthcare Centers, Food and Drug Administration (FDA), and/or other government officials/agencies may also need the information to make sure that the bamlanivimab and etesevimab is used in a safe and proper manner.

5. RISKS AND BENEFITS

5.1 What are the risks of being treated with bamlanivimab and etesevimab?
Allergic reactions can happen during and after the infusion. Signs and symptoms may include fever, chills, nausea, headache, shortness of breath, low blood pressure, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, and dizziness. Side effects of receiving any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site. It is possible that new, unanticipated, different, or worse symptoms will result from using bamlanivimab and etesevimab, including, but not limited to death.

5.2 What are the possible benefits of being treated with this bamlanivimab and etesevimab?
Expected benefit is that the patient will experience a decreased possibility of progressing from mild to moderate COVID-19 symptoms to sever symptoms and/or the need for hospitalization.

5.3 What is the most likely outcome of being treated with this bamlanivimab and etesevimab?
Unknown, as this drug is experimental and there is not information available at this time as to likely outcomes related to its use.

5.4 You are free to stop the bamlanivimab and etesevimab infusion at any time, and your treatment with it is voluntary. You should notify your nurse if you wish to stop the infusion and he/she can contact your doctor. You should discuss your choice with your doctor, as stopping its use may pose additional risks to you that your doctor may need to manage.

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6. SIGNATURE

Consent/Assent

I understand the information printed on this form. I have discussed this bamlanivimab and etesevimab, its risks and potential benefits, and my other choices with my Attending Physician. I agree with my physician that there are no approved or commonly used treatments for my COVID-19 infection, but that other treatment options are unlikely to be as helpful as bamlanivimab and etesevimab and are unlikely to prolong my life. I understand bamlanivimab and etesevimab is not yet FDA approved for use in COVID-19 infection, but is FDA authorized solely for emergency use as determined by the treating physician. My questions so far have been answered. I understand that if I have more questions or concerns, I may speak with my treating physician. If bamlanivimab and etesevimab makes me sick or causes me injury, I understand that I or my estate will be responsible for the costs of treatment. I understand that I will receive a copy of this consent and the FDA Fact Sheet regarding bamlanivimab and etesevimab at the time I sign it. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued treatment.

Legal Name of Patient/Authorized Representative, If Patient Cannot Consent:

_____

Signature: _____

Date of Signature (mm/dd/yy): _____

Relationship to patient: ☐ Parent ☐ Spouse ☐ Child ☐ Sibling ☐ Legal guardian ☐ Other

If "Other," explain: _____

Reason patient is unable to consent: _____