Bartlett Regional Hospital

3260 Hospital Drive, Juneau, Alaska 99801 907.796.8900 www.bartletthospital.org

Informed Consent to Treatment with Emergency Use Authorization (EUA), Casirivimab-Imdevimab For Coronavirus Disease 2019 (COVID-19)

Overview

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved products casirivimab and imdevimab for treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in adults and children over the age of 12 years who do not have severe enough disease to be hospitalized.

Casirivimab and imdevimab are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Casirivimab and imdevimab under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3.

Casirivimab / imdevimab Information: Casirivimab and imdevimab are investigational drugs and are not currently approved for any indication. Casirivimab and imdevimab are monoclonal antibiodies that act to neutralize SARS-CoV-2.Your physician is required to get your signature on this form and keep this form in your patient record.

Consent Statement

I,_____an adult (or legal guardian of)_____consent to the use of Casirivimab and imdevimab for my treatment based on Bartlett Regional hospital protocol for Casirivimab and imdevimab EUA. I am aware of the route of administration of Casirivimab and imdevimab, possible side effects, risks and discomforts, other treatment options, and potential outcomes of being treated with Casirivimab and imdevimab. I understand that there is no final FDA approval or concluded research proof of the effectiveness of treatment with Casirivimab and imdevimab. It is possible that I may experience new, unanticipated, different or worse symptoms with the use of these drugs. It is also possible that death could be hastened with treatment or use of these EUA/Investigational drugs.

The manufacturer of Casirivimab and imdevimab, the pharmacy or other distributor of the drug, and the patient's treating physician or Bartlett Regional Hospital are not liable for or subject to any of the following for an act or omission related to providing, distributing or treating you with Casirivimab and imdevimab unless the act or omission constitutes willful or wanton misconduct: damages in any civil action, prosecution in any criminal proceeding or professional disciplinary action.

Participation in this treatment with Casirivimab and imdevimab is voluntary. I may begin withdrawal from treatment at any time. Certain investigational drugs, products or devices may necessitate a gradual withdrawal for your health and safety. There is no monetary penalty or loss for withdrawal from treatment other than the cost of the investigational drug, product or device already dispensed

In certain circumstances my participation in Casirivimab and imdevimab use may be terminated at any time by my physician based on clinical judgement without regard to my consent.

Confidentiality. My personal health information including the results of your treatment may be subject

to inspection by or disclosure to the manufacturer of Casirivimab and etesevimab as well as the FDA. This may occur because the drug is in clinical trials within the FDA approval process.

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Confirmation of Understanding and Statement of Consent by Patient/Representative

I have read and understand this consent document, Fact Sheets for Patients and Parent/Caregivers Emergency Use Authorization (EUA) of Casirivimab and imdevimab For Coronavirus Disease 2019 (COVID-19), and have been able to ask questions about my options for treatment and these EUA/investigational drugs, and my questions and concerns have been addressed.

I give my informed and voluntary consent to participate in treatment with Casirivimab and imdevimab. I will be given a copy of this consent document for my records.

_____

Printed name of patient or patient's representative

_____ _____ _____

Signature of patient or patient's representative Date Time

Witness Attestation

I have witnessed the signing of this consent form: (Please check one.)

☐ in-person ☐telephone

_____

Printed name of witness

_____ _____ _____

Signature of witness Date Time

_____

Physician

I have explained the above informed consent form to the patient or the patient's representative including the risks involved with using the EUA/investigational drugs, Casirivimab - imdevimab. A copy of this form has been given to the patient or the patient's representative.

_____

Printed name of Physician

_____ _____ _____

Signature of Physician Date Time