BAYLOR SCOTT & WHITE HEALTH
INFORMED CONSENT FOR CASIRIVIMAB AND IMDEVIMAB
CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration ("FDA") has issued an Emergency Use Authorization ("EUA") of casirivimab and imdevimab ("drug") for treatment of COVID-19. This drug is an investigational medicine to treat certain people with mild to moderate COVID-19 but are at high risk for severe COVID-19 and subsequent hospitalization. This drug is investigational because it is still being studied. There is limited information known about the safety and effectiveness of using this drug to treat people with COVID-19. Currently, there are limited FDA approved products available to treat COVID-19.

There may be risks and side-effects involved with taking this drug, both known and unknown. These may be a minor inconvenience or may be so severe as to cause sudden death. Receiving this drug is voluntary and you can refuse to receive this drug now or at any point.

I (we) believe all of my (our) questions have been answered to my (our) satisfaction and I (we) believe that I (we) have sufficient information to give this informed consent to the use of this drug. I have been provided an opportunity to read, been provided a copy, and/or declined a copy of the FDA Fact Sheet for Patients and Parents/Caregivers. I have had the opportunity to ask questions and I understand the benefit and risk of this drug.

I (we) understand that treatment with this that is planned for me and I (we) voluntarily consent and authorize this treatment.

I (we) certify this form has been fully explained to me, that I (we) have read it or have had it read to me, that the blank spaces have been filled in, and that I (we) understand its contents.

DATE: _____ TIME: _____ A.M. / P.M.

PATIENT/OTHER LEGALLY RESPONSIBLE PERSON:

_____ _____
Signature Print Name

WITNESS/PHYSICIAN:

_____ _____
Signature Print Name

_____
Address

_____
City, State, Zip Code

FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF CASIRIVIMAB AND IMDEVIMAB FOR CORONAVIRUS DISEASE 2019
(COVID-19)

You are being given a medicine called **casirivimab** and **imdevimab** for the treatment of coronavirus disease 2019 (COVID-19). This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking casirivimab and imdevimab, which you may receive.

Receiving casirivimab and imdevimab may benefit certain people with COVID-19.

Read this Fact Sheet for information about casirivimab and imdevimab. Talk to your healthcare provider if you have questions. It is your choice to receive casirivimab and imdevimab or stop at any time.

WHAT IS COVID-19?

COVID-19 is caused by a virus called a coronavirus. 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 occur and may cause some of your other 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, seem to be 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 your other medical conditions to become worse.

WHAT IS CASIRIVIMAB AND IMDEVIMAB?

Casirivimab and imdevimab are investigational medicines used to treat mild to moderate symptoms of COVID-19 in non-hospitalized adults and adolescents (12 years of age and older who weigh at least 88 pounds (40 kg)), and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. Casirivimab and imdevimab are investigational because they are still being studied. There is limited information known about the safety and effectiveness of using casirivimab and imdevimab to treat people with COVID-19.

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

WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE I RECEIVE CASIRIVIMAB AND IMDEVIMAB?

Tell your healthcare provider about all of your medical conditions, including if you:

- Have any allergies

- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illnesses
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

HOW WILL I RECEIVE CASIRIVIMAB AND IMDEVIMAB?

- Casirivimab and imdevimab are two investigational medicines given together as a single intravenous infusion (through a vein) for at least 1 hour.
- You will receive one dose of casirivimab and imdevimab by intravenous infusion.

WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF CASIRIVIMAB AND IMDEVIMAB?

Possible side effects of casirivimab and imdevimab are:

- Allergic reactions. Allergic reactions can happen during and after infusion with casirivimab and imdevimab. Tell your healthcare provider or nurse, or get medical help right away if you get any of the following signs and symptoms of allergic reactions: fever, chills, low blood pressure, changes in your heartbeat, shortness of breath, wheezing, swelling of your lips, face, or throat, rash including hives, itching, headache, nausea, vomiting, sweating, muscle aches, dizziness and shivering.

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

It is possible that casirivimab and imdevimab could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, casirivimab and imdevimab may reduce your 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 healthcare provider if you have any questions.

WHAT OTHER TREATMENT CHOICES ARE THERE?

Like casirivimab and imdevimab, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.covid19treatmentguidelines.nih.gov/ for information on other medicines used to treat people with COVID-19.

It is your choice to be treated or not to be treated with casirivimab and imdevimab. Should you decide not to receive casirivimab and imdevimab or stop it at any time, it will not change your standard medical care.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

There is limited experience treating pregnant women or breastfeeding mothers with casirivimab and imdevimab. For a mother and unborn baby, the benefit of receiving casirivimab and imdevimab may be

greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

HOW DO I REPORT SIDE EFFECTS WITH CASIRIVIMAB AND IMDEVIMAB?

Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088 or call 1-844-734-6643.

HOW CAN I LEARN MORE?

- Ask your health care provider.
- Visit www.REGENCOV2.com
- Visit https://www.covid19treatmentguidelines.nih.gov/
- Contact your local or state public health department.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made casirivimab and imdevimab 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.

Casirivimab and imdevimab have 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 includes that there are no adequate, approved, 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 casirivimab and imdevimab 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).

REGENERON

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Authorized: 11/2020