PATIENT INFORMATION AND INFORMED CONSENT FORM

Name of Experimental Treatment: Remdesivir, GS-5734

Manufacturer: Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404
USA

Treating Physician

Name:_______________________________
Telephone:___________________________

WHY AM I REVIEWING THIS PATIENT INFORMATION AND CONSENT FORM?

Dr. ___________________________ is offering to treat you, or the patient you represent (in which case the word “you” will refer to the person you are representing) with an experimental treatment called remdesivir (GS-5734) because you have a serious condition with a newly identified coronavirus called SARS-2-CoV infection (also known as COVID-19) and there are no current approved treatments. SARS-2-CoV infection may result in a serious infection which could be fatal. SARS-2-CoV infected patients are currently managed with general supportive care. Standard therapies, such as antibiotics and approved anti-viral medications, are not effective in treating SARS-2-CoV infections.

This Patient Information and Informed Consent Form explains the experimental treatment to you. Your doctor or nurse will go over this form with you. Your doctor or nurse will answer all questions you have about the information in this form.

If you agree to use of the experimental treatment, you will be asked to sign and date this form. You will be given a signed and dated copy to keep. No one can force you to take part in this experimental treatment.

WHAT IS THE PURPOSE OF THIS EXPERIMENTAL TREATMENT?

Remdesivir is an experimental drug being developed by Gilead Sciences. In experiments, it has shown convincing activity against SARS-2-CoV and multiple other similar types of viruses.

Single Use – Remdesivir
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• An experimental drug is a drug that is not approved by the U.S. Food and Drug Administration (FDA).
• This treatment is considered experimental.
• Someone will explain this treatment to you.
• Whether or not you get this treatment is up to you.
• You can choose not to get this treatment.
• You can agree to get this treatment now and later change your mind.
• If you do change your mind, contact your doctor right away.
• Whatever you decide it will not be held against you.
• Feel free to ask all the questions you want before you decide.

HOW LONG WILL THIS EXPERIMENTAL TREATMENT LAST?

The experimental treatment will be given for 10 days.

WHAT HAPPENS IF I GET THIS EXPERIMENTAL TREATMENT?

The experimental treatment will be administered once a day for 10 days. The experimental drug will be given intravenously (through a vein in your arm) over 30 to 60 minutes, and blood may be collected for safety and treatment purposes.

The experimental treatment can be stopped at any time by the doctor or experimental drug manufacturer (Gilead Sciences) based on the assessment of the safety of the experimental drug.

If necessary, the doctor may determine that you require longer observation while you are in the hospital and request additional laboratory testing based on the effects of the experimental drug or the results of laboratory tests.

WHAT ARE YOUR RESPONSIBILITIES?

If you choose to get the treatment, there are some rules you must follow. Some of the rules are listed below. There could be other rules that your doctor will review with you.

• You must not get pregnant or get someone pregnant during this study.
• It is very important that you tell your study doctor all of the information you know about your health and medications you are taking now or start taking while in the study. If you do not tell the study doctor everything you know, you may be putting your health at risk.
• You must follow all instructions given to you while on treatment. If you are unsure about what you are supposed to do, ask your doctor.
IS THERE ANY WAY THIS EXPERIMENTAL TREATMENT COULD BE BAD FOR ME?

There may be risks involved with taking remdesivir, both known and unknown. These may be a minor inconvenience or may be so severe as to cause death.

Remdesivir is an investigational drug; it is not an approved drug. It is being studied for the treatment of infection by several viruses, including filoviruses and for COVID-19. There are risks involved with taking remdesivir.

As of 20 February 2020, 100 healthy people have taken remdesivir in clinical studies. In addition, more than 400 people have taken remdesivir to treat a viral infection. Most of these people had Ebola virus infection. Remdesivir has not been tested in people with COVID-19. Most of what we know about the safety of remdesivir comes from the studies of healthy people. Some of the studies are still blinded. That means that it is not known if the side effects happened to people who got remdesivir or placebo (a medically inactive compound used for comparison to remdesivir). The most common side effects that have been reported by more than five people in these studies were:

- Inflamed blood vessel
- Constipation
- Bruising
- Headache
- Pain in an arm or leg
- Nausea (feeling sick)

One very sick person who got remdesivir for the treatment of Ebola infection developed low blood pressure during remdesivir treatment and died shortly after. It is not known if this was due to remdesivir or due to Ebola disease.

Some people who took remdesivir had problems with liver blood tests, but this does not always happen. These tests can be a sign of problems with the liver. All the healthy people who took remdesivir and had problems with liver blood tests got better after they stopped taking remdesivir.

Remdesivir has been tested in animals. Some of the animals had kidney problems after taking remdesivir but these changes went away after remdesivir was stopped. Some animals also had local redness where remdesivir was injected. It is not known if what happens in animals will also happen to people.

Please talk to your study doctor for more details on side effects.
BLOOD SAMPLING

Collecting a blood sample from a vein may cause pain, swelling and/or bruising at the insertion site of the needle. Lightheadedness, and/or fainting may also occur during or shortly after the draw. Although rare, localized blood clot formation, infections and nerve damage may occur.

INTRAVENOUS DOSE ADMINISTRATION

The experimental drug will be given through an intravenous (IV) catheter placed in your arm vein. Medications administered into veins (intravenously) may cause pain, bruising, swelling, redness and very rarely, infection at the site of administration.

ALLERGIC REACTION

Allergic reaction is always possible with a drug you have not taken. Serious allergic reactions that can be life-threatening may occur. Some things that happen during an allergic reaction to any type of medication are:

- rash
- having a hard time breathing
- wheezing when you breathe
- sudden drop in blood pressure
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

UNKNOWN/UNEXPECTED RISKS AND DISCOMFORTS

There are adverse events that are not known or happen rarely when patients take an experimental drug. You will be told of any new information that might cause you to change your mind about continuing to take part in this experimental treatment.

As with any new drug, extra care will be taken to monitor the side effects that are not always obvious. If you feel any side effects or unusual symptoms, please notify your doctor as soon as possible at the phone number listed in this form.

PREGNANCY AND BREASTFEEDING

We do not know the effects of remdesivir on an unborn baby or a nursing infant. If you are a woman who is pregnant or intends to become pregnant, or if you are currently nursing (breastfeeding) a child, you cannot receive this treatment. You should know that on rare occasions in early pregnancy, the pregnancy test may be falsely negative.
If you or your partner become pregnant while you are taking remdesivir, you must tell your doctor immediately. We do not know what the risk to you and your baby is, so you/your partner should get medical supervision during any pregnancy and for the baby after it is born. The drug manufacturer and you or your partner’s doctor will not be responsible for the costs related to your pregnancy, delivery, or care of your child.

The drug manufacturer will collect information about your pregnancy and the outcome of your pregnancy.

**WHAT ARE THE POSSIBLE BENEFITS OF THIS EXPERIMENTAL TREATMENT?**

You may not receive any direct medical benefit from taking this experimental drug. Animals infected with a similar virus called SARS had better outcomes compared to animals who did not receive the drugs. It is unknown whether the same beneficial effects will be seen in people.

**WHAT ARE YOUR TREATMENT OPTIONS?**

Your alternative is to not take part in this experimental treatment. You will continue to receive general supportive care under the care of your doctor.

**WHAT HAPPENS IF YOU NO LONGER WANT TO TAKE PART IN THE EXPERIMENTAL TREATMENT?**

Your decision to take part in this experimental treatment is voluntary. You can refuse to take part or stop taking part at any time without giving a reason. There will be no penalty or loss of benefits to you. If you decide to stop the experimental treatment at any time, your exit from the experimental treatment will not affect medical care which you otherwise may receive.

This experimental treatment may be stopped at any time by your doctor or regulatory authorities.

Your doctor may decide for your medical safety to stop your experimental drug or take you off the experimental treatment. You may be taken off the experimental treatment if your doctor learns you did not give a correct medical history or did not follow instructions for the experimental treatment. If you are taken off the experimental treatment, you will no longer receive the experimental drug. If your experimental drug is stopped, your doctor will closely monitor your overall health.

**HOW MUCH WILL THE EXPERIMENTAL TREATMENT COST YOU?**

The experimental drug used in this treatment will be given to you at no charge. You may be responsible for fees for lab tests and procedures.
You or your usual health care payer will be responsible for any other health care costs.

WHAT HAPPENS IF YOU ARE INJURED?
If you become sick or injured as a direct result of taking the experimental drug and/or following the procedures, the site/treating doctor will provide you with medical treatment. You should immediately contact your doctor at the contact information shown on the first page of this form in the event you experience any experimental treatment-related illness or injury.

You do not give up any legal rights by signing this form. You are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the experimental treatment.

GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE EXPERIMENTAL TREATMENT

You can ask questions about this information and consent form at any time (before you decide to start the experimental treatment, at any time during the treatment, or after completion of the experimental treatment). Questions may include:

- Who to contact in the case of an experimental treatment-related injury or illness;
- Your responsibilities as a patient;
- Eligibility to participate in the experimental treatment;
- The doctor’s or site’s decision to exclude you from participation;
- Results of tests and/or procedures;
- Other questions, concerns, or complaints.

Contact the doctor listed on the first page of this form with any questions, concerns or complaints.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS

If you have any questions about your rights as a patient, or have general questions about what it means to be treated with an experimental drug or if you sustain any complications or injuries, please contact the Saint Joseph Mercy Health System Research Compliance Department at (734) 712-5470 and ask to speak with the Director of Research Compliance.

WHO WILL HAVE ACCESS TO YOUR MEDICAL RECORDS and how will they be kept confidential?
Records identifying you will be kept confidential and, to the extent permitted by applicable laws and/or regulations, will not be made publicly available. In the event of
any publication regarding this experimental treatment, your identity will remain confidential.

Representatives from government agencies, including the U.S. Food and Drug Administration (“FDA”), institutional review boards, the drug manufacturer (Gilead Sciences) and/or the Manufacturer’s authorized representatives may need access to your original medical records for the purpose of checking data collected for the experimental treatment. By signing this consent form, you authorize the use or disclosure of your health information as follows:

A record of your progress will be kept in a confidential file at ______________________ (Name of treating hospital location). Only those people who work on treating you will see any records that could identify you. These people may copy all or part of your records related to this treatment. The hospital takes its responsibility to protect your health information from unnecessary disclosure very seriously. Your name or any other identification will not be used in any published reports or presentations to the public.

Your coded information may also be used for additional unanticipated medical and/or scientific research projects in the future relating to your disease or similar diseases and development of the experimental drug (but at all times in compliance with applicable laws and regulations).

In the unfortunate event of your death, it may be necessary for your doctor to collect medical records leading up to and/or related to your death. Such information may include information about remdesivir. In addition, a copy of the death certificate and a copy of the autopsy report (if an autopsy is performed) will be requested. The obtained information may be reported to the drug manufacturer and regulatory authorities.

In summary:

I consent to my personal information, collected in relation to my treatment, being passed to Gilead Sciences, manufacturer of the Drug, and Gilead Sciences’ use of such data for any legal purpose, including in connection with the filing of regulatory documents or applications with any government authority. I understand that this will involve the transfer and processing of my personal data to the regulatory authorities of the United States government and other countries where laws may not protect my privacy to the same extent as in my country. However, I understand that Gilead Sciences has confirmed that it will take all reasonable steps to protect my right to privacy.
AGREEMENT TO BE IN THE EXPERIMENTAL TREATMENT

By signing this informed consent form, I acknowledge that:
(1) I have carefully read and understand the information in this form.
(2) The purpose and procedures of this treatment have been fully explained to me. I was able to ask questions and all of my questions were answered to my satisfaction.
(3) I have been informed of the experimental use of the drug and associated procedures.
(4) I have been informed of possible risks as a result of taking part in this experimental treatment that could happen from both known and unknown causes.
(5) I understand that I am free to withdraw my consent and to stop my participation in this experimental treatment at any time. The possible effect on my health, if any, of stopping the experimental treatment early has been explained to me.
(6) I understand that stopping the experimental treatment will not impact my medical care and treatment options.
(7) I authorize the release of any health information to Gilead pertaining to medical history, or physical condition and treatment received. I understand that if the person or entity that receives the information is not a health care provider or health plan covered by federal privacy regulations, the information described above may be redisclosed and no longer protected by HIPAA regulations. This authorization expires two years after the signature date.

Patient

Printed Name -Patient  Signature  Date

Person Obtaining Consent

Printed Name  Signature  Date

Printed Legally Authorized Representative  Signature  Date

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