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## 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:**

**Additional Contact(s):**

### **WHY AM I REVIEWING THIS PATIENT INFORMATION AND CONSENT FORM?**

Dr. \_\_\_\_\_ is offering to treat you, your child (in which case the word “you” will refer to “your child” throughout this document), or your representative (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 and there are no current approved treatments. SARS-2-CoV infection may result in a serious infection. SARS-2-CoV infected patients are currently managed with general supportive care.

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.
- An experimental drug is a drug that is not approved by the U.S. Food and Drug Administration (FDA).
- This treatment is considered experimental and research.

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- 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 a 30 minute to 1 hour period, 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 in the clinic or 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.

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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. 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; they 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 DRAWS**

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 clot formation, infections and nerve damage may occur.

## **INTRAVENOUS DOSE ADMINISTRATION**

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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 has to 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 RDV 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 be in this study. 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 RDV, 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 Sponsor 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 Sponsor will collect information about your pregnancy and the outcome of your pregnancy.

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### **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.

### **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.

Your participation in this experimental treatment may be stopped at any time by your doctor, Gilead Sciences, Inc., 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

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

### **GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS**

This experimental treatment has been reviewed by an Institutional Review Board (IRB) or Ethics Committee (EC). This Committee reviewed this experimental treatment to help ensure that your rights and welfare are protected and that this experimental treatment is carried out in an ethical manner.

For questions about your rights, contact:

- IRB or EC address:
- Phone:
- E-mail:

### **WHO WILL HAVE ACCESS TO YOUR MEDICAL RECORDS?**

### **GENERAL STATEMENT ABOUT PRIVACY**

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 Manufacturer 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 this access.

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).

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**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 research 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 drugs and procedures 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.
- (4) 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.
- (5) I understand that stopping the experimental treatment will not impact my medical care and treatment options.

**Patient, Legally Authorized  
Representative, Parent, or Guardian of  
a Child**

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Printed Name

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Signature

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Date**Person Obtaining Consent**

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Printed Name & Title

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Signature

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Date**Witness (if applicable)**

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Witness Printed Name

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Signature

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Date