SUBJECT INFORMATION AND INFORMED CONSENT FORM AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

WHAT IS A CLINICAL RESEARCH STUDY?

You have been asked to take part in a clinical research study. This study will compare two experimental drugs, named SOF/VEL/GS-9857 FDC (Fixed-Dose Combination) and SOF/VELFDC for 12 weeks for the treatment of chronic hepatitis C virus (HCV) infection. An experimental drug is one that is currently being tested and has not been approved by the Food and Drug Administration (FDA) for use in the United States. Experimental drugs may be tested in research studies such as this one. This Subject Information and Informed Consent Form will explain the study to you. Your study doctor or study nurse will go over this form with you. Your study doctor or study nurse will answer all questions you have about the information in this form. If you agree to take part, 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 study.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to determine the efficacy, safety, and tolerability of sofosbuvir(SOF)/velpatasvir (VEL)/GS-9857 in comparison with SOF/VEL in subjects infected with HCV. Information about any side effects that may occur will also be collected.

HOW LONG WILL YOU BE ON THE STUDY?

Your participation in this study will last about 36 weeks, not including the screening period. During this time, you will be required to visit the clinic at least 9 times (not including this visit).

WHAT ARE THE POSSIBLE RISKS OF BEING IN THIS STUDY?

COMMON SIDE EFFECTS FOR SOF/VEL/GS-9857

The safety profile for the 3 drug combination of SOF 400 mg, VEL 100 mg, and GS-9857 100mg (SOF/VEL/GS-9857), is based on the safety information from 3 Phase 2 clinical studies in which SOF/VEL, together as a single pill, was given with GS-9857 to over 420 HCV infected subjects. In these studies, SOF/VEL and GS-9857 were given for 4 to 12 weeks. Most of the side effects were considered to be mild. The most common side effects ($\geqslant$ 10%) reported by subjects taking SOF/VEL and GS-9857 together were:

- Headache (23%)

• Nausea (17%)

• Fatigue (tiredness) (17%)

• Diarrhea (15%)

Three subjects decided on their own to stop taking SOF/VEL and GS-9857 because of side effects. One subject stopped SOF/VEL and GS-9857 treatment because of moderate tiredness(fatigue). The second subject stopped SOF/VEL and GS-9857 treatment because of moderate diarrhea and moderate vomiting which caused the subject to have mild water loss from the body(dehydration) and moderate feelings of weakness (asthenia). The third subject stopped SOF/VEL and GS-9857 due to moderate stomach irritation (gastritis).

There were no serious drug-related side effects reported by subjects taking SOF/VEL and GS-9857. However, one subject experienced a serious side effect (atrial fibrillation) 1 day after completing 3 days of GS-9857 alone; this event was considered related to study drug by the study doctor. For people that are lactose intolerant, please note that combined SOF/VEL/GS-9857 tablets contain small amounts (less than 400 milligrams per tablet) of lactose. It is unknown whether this amount of lactose may lead to symptoms of lactose intolerance. For comparison, one cup of low-fat milk contains 12,000 milligrams of lactose

COMMON SIDE EFFECTS FOR SOF/VEL

The safety profile of SOF/VEL is based on the combined safety information from 3 Phase 3 clinical studies. In these studies, 1035 HCV infected subjects took the fixed dose combination of SOF/VEL (400mg/100 mg) for 12 weeks.

Most side effects reported by subjects taking SOF/VEL for 12 weeks were mild. The most common side effects ($\geqslant$ 10%) reported when SOF/ VEL was given to 1035 subjects were:

• Headache (29%)

• Fatigue (tiredness) (25%)

• Nausea (14%)

• Nasopharyngitis or cold symptoms (12%)

Only 2 (0.2%) of the patients taking SOF/VEL stopped treatment because of side effects in these studies. There were no serious drug-related side effects reported in any of the patients taking SOF / VEL. It is not expected that you will have any of these side effects. Other side effects may occur that are not listed here or were not seen before. Please speak to your study doctor for more information. Side effects are usually temporary and can often be treated. However, it is very important that you report all side effects to your study doctor as it is possible that side effects may suggest a serious or fatal health problem.

VIRAL RESISTANCE

Treatment with drugs that directly inhibit the hepatitis C virus has been shown to lead to development of hepatitis C virus that is resistant to that drug and other drugs with the same type of action (such as protease inhibitors). These resistance mutations have been observed in the body as late as 4 to 5 years after treatment has ended. It is unknown whether having these resistance mutations might reduce the chance of treatment success with future drugs with the same type of action or with different types of action. It is possible that if you are treated with the drugs in this study and treatment doesn't work, you might have resistance mutations that would make future treatment less successful.

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 any 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 subjects take these study drugs. You will be told of any new information that might cause you to change your mind about continuing to take part in this study.

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 study doctor as soon as possible at the phone number listed on the first page of this form

WHAT HAPPENS IF YOU ARE INJURED?

MEDICAL TREATMENT AND COMPENSATION FOR STUDY-RELATED INJURY

If you become sick or injured as a direct result of taking the study drug and/or following the study procedures, the study site will provide you with medical treatment. The Sponsor, Gilead Sciences, Inc., will reimburse you or the study site for the reasonable and necessary costs of such medical treatment,

provided that you have followed the instructions of the Study Doctor. No other form of reimbursement for study-related injury or illness is offered by the Sponsor. You should immediately contact your Study Doctor at the contact information shown below in the event you experience any study-related illness or injury.

AGREEMENT TO BE IN THE STUDY

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 study 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 drugs and procedures of the study that are being tested. I have been informed of possible risks as a result of taking part in this study 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 study at any time. The possible effect on my health, if any, of stopping the study early has been explained to me. (5) I understand that stopping the study will not impact my medical care and treatment options.