A Retrospective/Prospective Study to Assess Safety, Tolerability, and Efficacy of Sofosbuvir based Direct Acting Antiviral (DAA) Therapy for Hepatitis C Treatment in HIV/HCV Coinfected Subjects Pre or Post Liver Transplant

INFORMED CONSENT: RETROSPECTIVE SUBJECTS

VERSION 3.0 July 11, 2017

Study Sponsor(s): The National Institute of Allergy and Infectious Diseases (NIAID)

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Clinical Trial Phase: Phase IV (non-IND)
Study Drug Provider: Gilead Sciences
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RETROSPECTIVE ARM

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CONSENT VERSION 1.0 /July 11, 2017
PROTOCOL VERSION 3.0 /July 11, 2017

[NOTE: Site specific sections are identified in bold italics, and will be tailored at each center accordingly]

INTRODUCTION

We invite you to take part in a medical research study at the ***[NAME OF CENTER].*** Your study doctor(s) **[NAMES, MD]** from the **[NAME OF CENTER]** will explain the study to you.

You are being asked to take part in this study because you are HIV positive and you were treated for hepatitis C using a sofosbuvir based direct acting antiviral (DAA), and you had decompensated liver disease at the time of that treatment. The researchers would like to learn more about how the treatment worked. About 50 people will participate in this study.

Why is this study being done?

The researchers have a study that is enrolling people with HIV and hepatitis C and liver disease. The study involves treating patients with a sofosbuvir based DAA to treat their hepatitis C. You are being asked to participate in a separate arm of that study since you were already treated with a similar drug for your hepatitis C. This will help the researchers learn more about long term outcomes in the treatment of hepatitis C in people with HIV who have or had liver disease.

The safety, tolerability and efficacy of SOF/LDV have not been established in patients with decompensated cirrhosis (clinical evidence of cirrhosis such as internal bleeding, fluid in the belly, or yellowing of the eyes and skin) or after liver transplantation. The purpose of this study is to determine whether SOF/LDV in combination for 12 to 24 weeks can be safe, tolerated and effective for treating HCV infection before or after liver transplantation in people who also have HIV infection. This drug works by blocking the HCV from dividing in your body.

What will happen if sign this form?

When you sign this form, you are giving consent for three things:

- The investigators will take information from your **[site name]** medical records and enter the data into a database. This information will be kept indefinitely, unless you withdraw your permission. It will be anonymous and confidential. The data collection will end by December of 2018.
- You will be asked if you agree to allow the investigators and collaborators to contact you in the future once this short study is over, so they may obtain even longer follow-up data on how your hepatitis and liver are doing.
- Finally, if you agree, you will return to **[site name]** for a Fibroscan so that the researchers can see how your liver is doing now. If you have had liver staging by Fibroscan or liver biopsy within the previous 12 months, we will record the results and you would not need to return for a Fibroscan.

Declining to participate will have no influence on your present or future status as a patient in this clinic. You will receive the same care as any other patient seen in this clinic. There will be no penalty or loss of benefits to which you are

otherwise entitled.

Are there any risks to me or my privacy?

We will do our best to protect the information we collect from you. Information that identifies you will be kept secure. The data collected will not include details that directly identify you, such as your name or address. If this study is published or presented at scientific meetings, names and other information that might identify you will not be used.

Participation in research may involve some loss of privacy. However, your records will be handled as confidentially as possible. Access will be limited to the research team at [site name] and the doctor organizing the study. Your contact information will not be shared with anyone outside this clinic.

If you agree to come in for a FibroScan®: The FibroScan® technique will be used to measure the amount of liver fibrosis in a non-invasive and painless manner. Performed at the bedside in the clinic, a machine will generate a pulse wave at the skin surface, which will spread through the liver. The speed of the wave will be measured by ultrasound. In general, the whole examination process can be completed within 15 minutes.

This Fibroscan® will be performed by technical personnel and/or hepatologist and the results will be reported to the investigators. There are no potential discomforts or risks involved with the Fibroscan procedure. However, according to the recommendations of use and based on safety and efficacy matters, pregnant women, patients with ascites (fluid in the abdomen), persons with active implantable medical devices and persons with a waist size more than 100cm will be excluded from this procedure.

Are there benefits to taking part in the study?

There is no direct benefit to you. However, the information from this study may help the researchers learn more about sofosbuvir based DAA therapy in the treatment of people with HCV and HIV that are pre or post liver transplant.

What other choices do you have if you do not take part in this study?

We encourage you to discuss this study with your physician and to explore other treatment options. Other treatment options for chronic HCV infection include other oral combinations of medications or choosing not to pursue treatment of HCV at this time.

Are there financial considerations?

There will be no cost or payment to you if you sign this form.

How will information about you be kept confidential?

Your medical records will be kept confidential to the extent allowed by the law. Your name or any other data that might identify you will not be used in any reports or publications resulting from this study. Because of your consent to participate, your medical records may be reviewed by NIH staff, by the study Sponsor and by the IRB (the body responsible for making sure that the study follows the guidelines for the protection of human research subjects) with the understanding that these records will be used only in connection with carrying out obligations relating to this clinical study. We will be routinely supplying information about you to your personal physician(s). You may change physicians whenever you like, but we need to have a physician with whom we can communicate about you. We would not ask your permission for each of these contacts.

What do I do if I have questions, now or later?

You can talk with the study researcher about any questions, concerns or complaints you have about this study. Contact the study researcher(s) _____ [name(s)] at _____ [telephone number(s)].

CONSENT

You have been given copies of the signed and dated consent form and the Experimental Subject's Bill of Rights to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in the study without jeopardy to your medical care. To participate, you should sign below.

I agree to return for a Fibroscan to see how my liver is now doing. There will be no cost to me.

Yes ☐ No ☐ _____ *Participant's Initials*

I agree to be contacted in the future by the investigators

Yes ☐ No ☐ _____ *Participant's Initials*

Preferred method of contact: ☐ phone: _____
☐ mail: _____
☐ email: _____

_____
Name of Participant

_____ _____
Signature of Participant Date

_____
Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date