SUBJECT INFORMATION SHEET AND INFORMED CONSENT FORM AND AUTHORIZATION (PERMISSION) TO USE AND DISCLOSE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES

Name of Research Study: AURORA: A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Cenicriviroc for the Treatment of Liver Fibrosis in Adult Subjects with Nonalcoholic Steatohepatitis

Study #: 3152-301-002

Sponsor: Tobira Therapeutics Inc., a subsidiary of Allergan plc
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South San Francisco, CA 94080
United States of America

Study Doctor Name: **David B Jack MD**

Research Site Address(es):

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Daytime Telephone Number(s): 801-816-3925

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You should keep a copy of this form. If you have any questions or problems during the study, call the phone number(s) above.

INTRODUCTION

You are being invited to take part in a nonalcoholic steatohepatitis (NASH) study. Steatohepatitis is a type of liver disease known as fatty liver where the cells in the liver have abnormal accumulation of fat. One common form of fatty liver disease is caused by drinking too much alcohol. However, another form of fatty liver not caused by increased alcohol consumption is called nonalcoholic fatty liver. Liver fibrosis is a condition developed as a consequence of inflammation and build-up of scar tissue in the liver. This is a research study conducted to identify whether the study drug called cenicriviroc (CVC) is safe and effective for the treatment of such a condition. Based on your medical history, you may be eligible as a subject with NASH, with suspected or diagnosed liver fibrosis. Taking part in this study is strictly voluntary, meaning that you may or may not choose to take part. Before you agree to be in this study, we ask you to read the following information carefully. It is important that you ask as many questions as you need to understand what is involved in this study. Therefore, take as much time as you need to decide whether you want to take part in this study or not.

Taking part in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to collect information about a medical treatment. Being in this study does not replace your regular medical care, but you may have additional evaluations or changes in your treatments during the study.

If you do not take part in the study, you will not lose any benefits or medical care you are entitled to have. If you decide to take part, you are free to stop taking part at any time and without having to give a reason. If you decide to stop taking part, you should tell the study staff immediately, even if between visits. The study staff may request you to come back for a safety follow up visit. There will not be any penalty or loss of benefits to you if you decide not to take part or if you leave the study early.

This document is called an informed consent form, and explains the following about the study:

- Purpose
- Medical procedures
- Potential benefits
- Potential risks, discomforts and precautions
- Your rights and responsibilities as a study subject

Medical information will be collected about each person who participates in this study. This form will explain how your medical information will be used and who may see it. If you wish to allow your medical information to be collected, used and shared with certain persons involved in the study, you will be asked to sign this form. If you do not sign this form, you will not be able to take part in this study.

The study is being done for a biopharmaceutical company called Tobira Therapeutics Inc., a subsidiary of Allergan plc. (the Sponsor). Tobira Therapeutics Inc., a subsidiary of Allergan plc the sponsor of this study, is providing financial support and material for

this study and is paying for the study doctor to conduct this study. Any questions you have about other financial arrangements between the sponsor and the study doctor or other study staff can be discussed with the study doctor.

If you agree, your general practitioner will be informed about your participation in this study.

PURPOSE OF THE STUDY

The study will be done at about 425 study centers in North, Central, and South America; Europe, Israel and Asia Pacific. About 2000 men and women, 18 to 75 years old, will participate in the study.

CVC is an investigational drug. This means that CVC is still being studied. It also means that the Food and Drug Administration (FDA) or other Regulatory Authorities have not approved CVC for the treatment of liver fibrosis in patients who have NASH.

This study is being conducted to identify:

- How effective CVC is when compared to a placebo for the treatment of liver fibrosis in patients with NASH. A placebo looks like the study drug but does not contain the study drug's active ingredient.
- How safe CVC is when compared to a placebo.

One dose (150 mg tablet) of CVC will be tested. This dose of CVC will be compared against placebo. You will be required to take one dose of CVC or placebo orally every day with food.

In this Informed Consent Form the term "study drug" refers to either CVC or placebo.

SUBJECT RESPONSIBILITIES

If you agree to participate in this study and are qualified to enroll in the study, you will have the following responsibilities:

- Follow the study staff's directions about the study
- Commit to attend all your clinic visits and complete the study tests and medical procedures
- Take the study drug as directed
- Give blood samples and urine samples
- Tell your study doctor about any medicine that you are taking before taking any new medicine
- Tell your study doctor about any illnesses or injuries that happen during the study
- Tell your study doctor about any side effects or problems that you experience during the study
- Tell your study doctor if you plan to have any surgery or any other medical treatment or medical procedure
- Tell your study doctor about your upcoming commitments like planned vacations so that your doctor can let you know whether the clinic visit can be rescheduled

For your health and safety, it is important that you are completely honest with your study doctor while you take part in the study.

During the study, you will not be allowed to take certain prescription medicine, over-the-counter medicine, and herbal supplements. The study staff will discuss with you which medicine you cannot take during the study.

It's important to let the study staff know if, for any reason, you stop taking the study drug at any time during the study. You will be asked to return to the clinic as quickly as possible, but you may continue to participate in the study even if you stop taking the study drug for any reason. If you stop participating in the study, you will be asked to have the end-of-study testing done for your safety.

STUDY OVERVIEW

About 8 weeks before you may receive study drug you will be asked to visit the study center to make sure you are eligible to take part in this research study. This is called a screening visit.

This research study will be completed in two parts: Part 1 and Part 2. You may participate in either Part 1, Part 2 or both Parts, depending on when you enter the study.

In Parts 1 and 2, you will be assigned to receive either CVC or placebo. You will have a 2 to 1 chance of receiving active drug CVC (67%) versus placebo (33%). This selection will be done using a computer (called randomization). Neither you, the study staff, the study doctor, nor anyone at the Sponsor will know whether you are taking CVC or placebo. This is called "blinding". However, if there is an emergency and there is a need to know your study drug assignment so that you will receive the proper care, the study doctor and the study staff can find out whether you are taking CVC or placebo. This is known as "unblinding".

Part 1 of the study will last approximately 12 months after receiving your first dose of study drug. After your participation has been confirmed, you will return to the study center 6 times during Part 1 of the study to see your study doctor and to get your study drug. If you continue in the study after completing Part 1, you will enter Part 2, and you will continue to receive the same study drug as in Part 1. In Part 2 you will return to the study center every 3 months. Part 2 of the study will last approximately 7 years (84 months).

If you start the study directly in Part 2, the study will last approximately 7 years (84 months). After your eligibility has been confirmed you will have 6 visits to the study center for the first year and then every 3 months thereafter.

STUDY PROCEDURES

Before any study-related tests and procedures are performed, you will be asked to read and sign this consent form. If you have any questions about any of the tests mentioned in this section, you should ask the study doctor or study staff. You may be asked to give more blood or urine samples if the study doctor needs to repeat tests to see if you

meet the study requirements or if more testing is needed for your safety. Blood samples will be taken during the research study. Using a needle to remove blood from a vein is called "a blood draw". Wherever possible the same needle will be used to draw all the blood samples per single visit listed in this form, however, it may be necessary to try more than once to draw blood.

Most study visits may take up to 2 hours.

Part 1 and Part 2: Screening Visit (Visit 1)

After signing this consent form, you will be provided with educational materials regarding NASH and liver fibrosis, including information about diet and exercise. The study doctor will discuss with you information about liver biopsies that will be required during the study. The following tests and procedures will be performed to see if you qualify to participate in this study:

- The study doctor or study staff will ask you to list all the medicines that you are taking, including all prescription or nonprescription medications, including herbals and over-the-counter.
- The study doctor or study staff will ask you questions about how you have been feeling, and about all diseases, illnesses, allergies and operations that you have or have had in the past including questions about your NASH. They will also ask if you exercise and questions about your diet. Because some people who have allergy to aspirin may also be allergic to tartrazine, a yellow dye that is used in medicine and food, you will be asked about any past medication allergies to yellow dye, tartrazine, and aspirin.
- You will be asked about your age, sex, race, and ethnic origin.
- You will be asked about your history and/or current use of alcohol and daily coffee or tea intake.
- Your vital signs will be taken. This will include your heart rate (pulse), blood pressure, respirations (number of breaths), and temperature.
- Your height and body weight will be measured, including measurements of your hips and waist.
- A physical examination will be performed by the study doctor or study staff.
- Blood samples will be collected for laboratory tests to check your health status.
- Blood will be drawn to test for active Hepatitis B and C (viruses that affect the liver) infection, and HIV (Human Immunodeficiency Virus), which can cause AIDS. If you test positive for HIV, hepatitis B or C, we will notify you. If your body did not clear hepatitis C and you had active hepatitis C infection, you will not be able to participate in this research study unless it has been at least 3 years since you completed treatment that cleared the infection from your body. We are required to notify state health authorities of positive results as required by state law. If you do not want to be tested you should not take part in this research study.
- If you are a woman of child bearing potential, a urine sample will be taken to test for pregnancy. If your urine sample is positive, this result will be confirmed with a blood test. If confirmed positive, you will not be able to participate in the research

study. If you are a postmenopausal woman, blood will be drawn to test your follicle stimulating hormone (FSH). This is not required if you are female taking hormone replacement therapy or surgically sterile.

- A sample of your blood will be taken for assessments related to fibrosis.
- A sample of your blood will be stored for follow-up safety or exploratory testing.
- You may have imaging procedures done to evaluate any changes in your liver if the test is available at the study center. If this can be done you will be asked to fast (not eating any food or drinking anything, except for water) for 3 hours prior to your visit.

Sometime during the screening period, after your laboratory results have been reviewed and before the baseline visit, you will have a liver biopsy. If you have undergone a liver biopsy within the last 6 months, that liver biopsy sample may be used. The study doctor will discuss if this is a possibility with you.

You may have up to 3 liver biopsies during the research study.

After the results of your liver biopsy at Screening have confirmed that you have NASH with moderate to severe liver fibrosis and if you meet all of the study requirements, including laboratory tests, you will be allowed to proceed to the Baseline visit.

Part 1 and Part 2: Baseline Visit (Visit 2)

You will be asked to fast (not eating any food or drinking anything, except for water) for 8 hours prior to your visit. If you do not fast, your visit may have to be rescheduled or you will need to return to the study center for your blood to be drawn.

You will also be asked to not do strenuous physical activity (e.g., weight lifting, exhausting yard work, intensive workouts) for the 48 hours before your study visits. Strenuous physical activity right before your blood draw may affect your CPK (creatine phosphokinase) blood levels. Strenuous physical activity can lead to muscle inflammation which can increase your CPK levels (CPK can help monitor your muscle damage).

The following tests and procedures will be performed at the Baseline visit:

- You will be asked about how you have been feeling since your last visit and the study staff will review your current medicine.
- You will be asked about your past or current use of alcohol and how much coffee or tea you have been drinking.
- You will be asked to complete questionnaires on your general health and feelings of well-being.
- Your vital signs will be taken. This will include your heart rate (pulse), blood pressure, respirations (number of breaths), and temperature.
- Your body weight will be measured, including measurements of your hips and waist.
- You will be advised about diet and exercise.

- A physical examination will be performed by the study doctor or study staff.
- You will have a 12-lead electrocardiogram (ECG), which is an electrical tracing of your heart's activity. This is done while you are lying flat on your back.
- If you are a woman of child bearing potential, a urine sample will be taken to test for pregnancy. If your test results are positive, this will be confirmed with a blood test. If confirmed positive, you will not be able to participate in the research study.
- Blood samples will be taken for laboratory tests to check your health status.
- A blood sample will be taken to look for biomarkers related to your liver disease (additional substances in your blood that may increase or decrease due to the disease or the study drug).
- Blood will be drawn to test levels of fats and fat-like substances and analytes of metabolism in your body after fasting.
- A sample of your blood will be taken for assessments related to fibrosis.
- A blood sample will be taken to see if you have a certain gene called PNPLA3 rs738409. This is a gene that may be a risk factor for progression of steatohepatitis (fatty liver disease).
- A blood sample will be taken for storage for safety testing or exploratory analyses.
- Blood will be drawn to test for past exposure or immunity to Hepatitis B virus.
- You may have imaging done to evaluate the changes in your liver if the test is available at the study center. If this can be done you will be asked to fast (not eating any food or drinking anything, except for water) for 3 hours prior to your visit.
- You will be receiving your study drug that was assigned to you. You will need to take the study drug with food. The study center may or may not provide a light meal to take with your study drug. You need to plan to bring food to take with your study drug the day of your visit.
- You will be given study drug to take home.

Part 1

In addition to the Baseline Visit, you will visit the study center 5 more times. You need to come to some visits having fasted for 8 hours (Visits 4, 5 and 7). If you do not fast, your visit may be rescheduled or you will need to return to the center for your blood to be drawn.

You will also be asked to not do strenuous physical activity (e.g., weight lifting, exhausting yard work, intensive workouts) for the 48 hours before your study visits. Strenuous physical activity right before your blood draw may affect your CPK (creatine phosphokinase) blood levels. Strenuous physical activity can lead to muscle inflammation which can increase your CPK levels.

The following tests and procedures will be done at some or all these visits:

- You will be asked about how you have been feeling since your last visit and the study staff will review your current medicine.

- You will be asked about your past or current use of alcohol and how much coffee or tea you have been drinking.
- Your vital signs will be taken. This will include your heart rate (HR), blood pressure (BP), respirations (number of breaths), and temperature.
- Depending on how you have been feeling, a physical examination may be performed by the study doctor or study staff.
- You will be advised about diet and exercise.
- Your body weight will be measured, including measurements of your hips and waist (Visits 4, 5 and 7).
- If you are a woman of child bearing potential, a urine sample will be taken to test for pregnancy. If your test results are positive, this will be confirmed with a blood test. If confirmed positive, you will be taken off study and conduct the Early Discontinuation Visit.
- Blood will be drawn as follows:

    - Blood will be drawn to check your health status.
    - If you have consented, blood will be drawn to measure the amount of study drug in your blood. During Visits 4, 5 and 7, you will take your study drug under the supervision of your study doctor and not before you go to the study center. During Visits 4 and 7, you will need to remain at the study center from 1 to 2 hours. During Visit 5, from 2 to 6 hours.
    - Blood will be drawn to test levels of fats and fat-like substances and analytes of metabolism in your body after fasting (visits 4, 5 and 7).
    - Blood will be drawn to test for biomarkers related to your liver disease (additional substances in your blood that may increase or decrease due to the disease or the study drug) (Visits 4, 5 and 7).
    - A sample of your blood will be stored for follow-up safety or exploratory testing (Visits 5 and 7).
    - A sample of your blood will be taken for assessments related to fibrosis (Visits 5 and 7).

- You will have a 12-lead ECG while lying flat on your back (Visit 7).
- You will be asked to complete questionnaires on your general health and feelings of well-being (Visits 5 and 7).
- If possible at the study center, you may have imaging done to evaluate any changes in your liver (Visits 5 and 7).
- You must return all unused study drug at each study visit and you will be given study drug to take home.

Before moving into Part 2, at Visit 7, you will have a liver biopsy.

Assuming you feel comfortable with your response to study drug and your study doctor assesses the study drug has been safe, you will move into Part 2, and follow the procedures from on page 9 of this form.

Part 2

If you are new to the research study starting on Part 2, the following tests and procedures will be done for the first 12 months at some or all these visits:

In addition to the Baseline visit, you will visit the study center 5 times. You need to come to some visits having fasted for 8 hours (Visits 5 and 7). If you do not fast, your visit may be rescheduled or you will need to return to the center for your blood to be drawn.

You will also be asked to not do strenuous physical activity (e.g., weight lifting, exhausting yard work, intensive workouts) for the 48 hours before your study visits. Strenuous physical activity right before your blood draw may affect your CPK (creatine phosphokinase) blood levels. Strenuous physical activity can lead to muscle inflammation which can increase your CPK levels.

The following tests and procedures will be done at some or all these visits:

- You will be asked about how you have been feeling since your last visit and the study staff will review your current medicine.
- You will be asked about your past or current use of alcohol and how much coffee or tea you have been drinking.
- Your vital signs will be taken. This will include your heart rate (pulse), blood pressure, respirations (number of breaths), and temperature (Visits 3, 5 and 7).
- Depending on how you have been feeling, a physical examination may be performed by the study doctor or study staff (Visits 3, 5 and 7).
- You will be advised about diet and exercise (Visits 3, 5 and 7).
- Your body weight will be measured, including measurements of your hips and waist (Visits 5 and 7).
- If you are a woman of child bearing potential, a urine sample will be taken to test for pregnancy. If your test results are positive, this will be confirmed with a blood test. If confirmed positive, you will be taken off study and conduct the Early Discontinuation Visit (Visits 3, 5 and 7).
- Blood will be drawn as follows:
    - Blood will be drawn to check your health status (Visits 3, 5 and 7).
    - Blood will be drawn to test levels of fats and fat-like substances and analytes of metabolism in your body after fasting (Visits 5 and 7).
    - Blood will be drawn to test for biomarkers related to your liver disease (additional substances in your blood that may increase or decrease due to the disease or the study drug) (Visits 5 and 7).
    - A sample of your blood will be stored for follow-up safety or exploratory testing (Visits 5 and 7).
    - A sample of your blood will be taken for assessments related to fibrosis (Visits 5 and 7).
- You will have a 12-lead ECG while lying flat on your back (Visit 7).
- You will be asked to complete questionnaires on your general health and feelings of well-being (Visit 7).

- If possible at the study center, you may have imaging done to evaluate any changes in your liver (Visit 7).
- You must return all unused study drug at each study visit and you will be given study drug to take home.
- At Visit 7, you will have a liver biopsy.

Whether you were participating in Part 1 or started in Part 2, after Visit 7 (12 months after you started taking study drug), you will be asked to come to the study center every 3 months until the study ends. It is not possible to predict exactly when the study will end, and it may continue for approximately 6 years after the last study subject has been enrolled in the study. Depending on when you enter the study, you will be asked to remain in the study for 7 to 8 years.

You need to come to some visits having fasted for 8 hours (Visits 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 35). If you do not fast, your visit may be rescheduled or you will need to return to the center for your blood to be drawn.

You will also be asked to not do strenuous physical activity (e.g., weight lifting, exhausting yard work, intensive workouts) for the 48 hours before your study visits. Strenuous physical activity right before your blood draw may affect your CPK (creatine phosphokinase) blood levels. Strenuous physical activity can lead to muscle inflammation which can increase your CPK levels.

The following tests and procedures will be done at some or all these visits:

- You will be asked about how you have been feeling since your last visit and the study staff will review your current medicine.
- You will be asked about your past or current use of alcohol and how much coffee or tea you have been drinking.
- You will be advised about diet and exercise (Visits 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35 and end of study visit).
- Your vital signs will be taken. This will include your heart rate (pulse), blood pressure, respirations (number of breaths), and temperature (Visits 9, 11,13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35 and your end of study visit).
- Depending on how you have been feeling, a physical examination may be performed by the study doctor or study staff (Visits 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35 and end of study visit).
- Your body weight will be measured, including measurements of your hips and waist (Visits 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33 and 35).
- If you are a woman of child bearing potential, a urine sample will be taken to test for pregnancy. If your test results are positive, this will be confirmed with a blood test. If confirmed positive, you will be taken off study and conduct the Early Discontinuation Visit. (Visits 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35 and your end of study visit).
- Blood will be drawn as follows:

  - Blood will be drawn to check your health status (Visits 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35 and your end of study visit).
  - Blood will be drawn to test levels of fats and fat-like substances and analytes of metabolism in your body after fasting (Visits 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33 and 35).
  - Blood will be drawn to test for biomarkers related to your liver disease (additional substances in your blood that may increase or decrease due to the disease or the study drug) (Visits 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33 and 35).
  - A sample of your blood will be stored for follow-up safety or exploratory testing (Visits 11, 15, 19, 23, 27, 31 and 35).
  - A sample of your blood will be taken for assessments related to fibrosis (Visits 11, 15, 19, 23, 27, 31 and 35).

- You will have a 12-lead ECG while lying flat on your back (Visits 11, 15, 19, 23, 27, 31 and 35).
- You will be asked to complete questionnaires on your general health and feelings of well-being (Visits 11, 15, 19, 23, 27, 31 and 35).
- If possible at the study center, you may have imaging done to evaluate the changes in your liver (Visits 11, 15, 19, 23, 27, 31 and 35).
- An ultrasound will be performed at Visit 23 and at your end of study visit to check the health of your liver.
- You will have a liver biopsy at Visit 23, or, if you have taken study drug for at least 6 months and have not had a liver biopsy at visit 23, you will have a liver biopsy at your end of study visit, if feasible.
- You must return all unused study drug at each study visit and you will be given study drug to take home.

Follow-up Visit

Approximately 1 month after your last dose of study drug you will need to return to the study center for a Follow-up visit. You will not take study drug during this period. At the last visit, you will have blood samples taken and medical tests performed. Following this visit, your study participation is complete.

The following procedures will be conducted at this visit:

- You will be asked about how you have been feeling since your last visit and the study staff will review your current medicine.
- You will be asked about your past or current use of alcohol and how much coffee or tea you have been drinking.
- You will be advised about diet and exercise.
- Your vital signs will be taken. This will include your heart rate (pulse), Blood pressure, respirations (number of breaths), temperature.
- Depending on how you have been feeling, a physical examination may be performed by the study doctor or study staff.
- A blood sample will be taken for laboratory tests to check your health status.

- If you are a woman of child bearing potential, a urine sample will be taken to test for pregnancy. If your test results are positive, this will be confirmed with a blood test.

Early Discontinuation Visit

If, for any reason, you stop participating in the study before your last treatment visit, you will be asked to come into the clinic. You will be asked to have all end-of-study testing done for your safety within 48 hours of taking your last dose of study drug.

The following tests and procedures will be done at the Early Discontinuation visit:

- You will be asked about how you have been feeling since your last visit and the study staff will review your current medicine.
- You will be advised about diet and exercise.
- Your vital signs will be taken. This will include your heart rate (pulse), Blood pressure, respirations (number of breaths), temperature.
- Depending on how you have been feeling, a physical examination may be performed by the study doctor or study staff.
- A blood sample will be taken for laboratory tests to check your health status.
- If you are a woman of child bearing potential, a urine sample will be taken to test for pregnancy. If your test results are positive, this will be confirmed with a blood test.
- Depending on the reason that you are stopping the study early, blood may be drawn for PK testing (measuring the amount of study drug in your blood), if you have previously consented to this.
- If you discontinue study drug early and have received study drug for at least 6 months, then a liver biopsy should be taken within 1 month of discontinuation, if feasible.
- If you discontinue study drug early and you have not completed visit 23, then an ultrasound should be taken, if feasible.
- You must return all unused study drug.

  If study drug is stopped, based on your or your Study Doctor's choice, you will be asked to continue to attend study visits or be otherwise contacted, unless you decide to withdraw completely from the study. If you stop taking part in the study completely, it is recommended that you go through the study withdrawal procedures that the Study Doctor considers necessary. After that, you would no longer be contacted about the study and no new information would be collected from you. However, information on your vital status may be collected from publicly available sources when the study data is being analyzed. If you have a side effect at your final study visit or withdrawal visit, then your Study Doctor may wish to contact you and ask you about this, until it has completely resolved. The Study Sponsor may also ask the Study Doctor for this information.

Blood Draws

During Part 1 of the research study, approximately 210 mL (about 1 cup) of blood will be drawn from you.

If you continue from Part 1 to Part 2, approximately 60 mL (about one quarter of a cup) of blood will be drawn annually. A total volume of approximately 630 mL (about 2.5 cups) of blood will be drawn from you continuing from Part 1 to Part 2 with approximately 96 months (8 years) of treatment.

If you are only participating in Part 2, approximately 160 mL (about two thirds of a cup) of blood will be drawn from you during your first year of treatment, and approximately 60 mL (about one quarter of a cup) of blood will be drawn annually thereafter. A total volume of approximately 520 mL (about 2 cups) of blood will be drawn with approximately 84 months (7 years) of treatment.

Additional blood samples for pharmacokinetic analysis (to measure the amount of study drug in your blood) may also be taken in Part 1. In addition, if you are participating in Part 2, if you finish the study early you will be asked to provide a blood sample for pharmacokinetic analysis. If you agree to these samples, please consent on page 22 of this form. You can still participate in the main research study, if you wish not to participate in this blood sampling.

Some blood samples may be required for a voluntary sub-study, at the baseline visit for potential future pharmacogenetic analysis. If you agree to also participate in this sub-study you will need to sign a separate consent (see separate pharmacogenentic informed consent form). You can still participate in the main research study, if you wish not to participate in the sub-study.

POSSIBLE SIDE EFFECTS AND RISKS OF THE STUDY DRUG

Side Effects of CVC:

Because CVC is investigational, all of its possible side effects may not be known. There may be rare and unknown side effects. Some of these may be life-threatening. You must tell the study doctor or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study. Please see below the list of reported adverse events (medical conditions occurring during participation in clinical trials that may or may not be side effects) seen to date:

The common side effects reported in studies, after unique and multiple doses of CVC were the following:

- Diarrhea – condition in which feces are discharged from the bowels frequently and in a liquid form
- Nausea - a feeling of sickness with an inclination to vomit
- Joint pain
- Rash

- Vomiting
- Flatulence and Abdominal distention (gas) - abdominal bloating due to gas in the intestine
- Fever
- Joint swelling
- Asthenia - abnormal physical weakness or lack of energy
- Dermatitis contact - skin rash or irritation caused by touching something

Because in previous studies some patients experienced increases in enzymes that are found in the liver, you will be monitored for this throughout the research study. Elevations in these liver lab tests may be due to your medical condition (NASH) but also may potentially be due to CVC. Such elevation in liver function tests in the blood can be early signs of liver injury. Because of this possibility, some of the blood drawn will be used to measure liver tests, such as the liver enzymes alanine transaminase (ALT), aspartate transaminase (AST), alkaline phosphatase (ALP), and gamma-glutamyl transpeptidase (GGT); bilirubin (a yellow substance that is part of bile); prothrombin time (which measures how long it takes for your blood to clot); and lactate dehydrogenase (LDH, an enzyme involved in energy production that is also found in the liver). You will be asked to return for confirmatory tests, and additional blood draws may be required within 48-72 hours after your laboratory data are available that show abnormality requiring close monitoring.

To date, rare cases of possible autoimmune hepatitis have been observed in clinical studies of CVC. Autoimmune Hepatitis is a serious condition involving inflammation of the liver that occurs when your body's immune system turns against liver cells. Possible cases of autoimmune hepatitis have been observed in NASH patients treated with both CVC and placebo in previous studies. Signs and symptoms of autoimmune hepatitis can range from minor to severe, may come on suddenly and may include fatigue, abdominal discomfort, yellowing of the skin and whites of the eyes (jaundice), enlarged liver, abnormal blood vessels on the skin (spider angiomas), skin rashes, joint pains, and loss of menstruation in women. Contact your study doctor or study staff if you experience any of these or if you experience loss of appetite for food, nausea, rash, vomiting, diarrhea, itchiness, or fever.

It is unknown whether these reported side effects are directly related to study drug, CVC.

Because CVC is still being studied, information on possible side effects of the drug is not complete.

Placebo Risks

The placebo itself does not have any active ingredient. That means you are not receiving direct treatment for your NASH. There is a possibility your condition could become worse. The placebo contains tartrazine as well as the dye FD&C Yellow/Tartrazine Aluminum Lake. Tartrazine may cause an allergic reaction.

Imaging Risks

As part of this study, your doctor may perform a scan like ultrasound used in pregnancy which will measure how elastic your liver is. There are no risks involved as the procedure is painless and not invasive (it's not carried out inside your body and does not break skin).

Your doctor may evaluate your liver by magnetic resonance imaging (MRI), which uses a combination of a large magnet, radiofrequencies, and a computer to produce detailed images for your liver. Because the procedure uses a strong magnet, it is important you let your study doctor know of any metal or electronic devices in your body, such as a cochlear implant or a bullet or shrapnel. If there is a possibility that you are claustrophobic, then you can speak to your doctor about options to help you reduce your anxiety before your MRI exam.

Your study doctor will discuss the imagining technique they will use with you, including any potential risks and answer your questions

Ultrasound Risks

A small amount of gel will be put on your stomach and a probe moved across that area. The gel may feel a little cold and uncomfortable initially.

Unforeseen Risks

Since the study drug is investigational when taken alone or in combination with other medicine, there may be other risks that are unknown.

Sometimes people have allergic reactions to drugs. If you have a very bad allergic reaction, you could die. Some signs that you may be having an allergic reaction are:

- Rash or hives
- Having a hard time breathing
- Wheezing when you breathe
- Sudden change in blood pressure (making you feel dizzy or lightheaded)
- Swelling around the mouth, throat or eyes
- Fast pulse
- Sweating.

You should get immediate medical help and contact the study doctor or staff if you have any of these or any other side effects during the study.

Other Procedures

Liver Biopsy Risks

Up to 3 liver biopsies are planned for the research study. During the biopsy, the doctor will make a small incision on your upper abdomen and insert a needle to take a small sample of your liver. It will be a brief procedure to collect the sample. After the biopsy, you will be asked to lie in bed for several hours, and you should not drive for about 8 hours. You should also avoid any strenuous activity for a few days.

A numbing medicine (local anesthetic) may be used in the area the biopsy will take place or you may be given pain medicine. You may feel a brief sting or burn when the numbing medicine goes in your skin when applicable. When the biopsy needle is inserted, you may feel a deep pressure and a dull or sharp pain during this brief procedure.

After the numbing medicine wears off, you may feel a dull pain in your right shoulder. This is called referred pain and generally goes away in about 12 hours. Talk to your doctor before you take a non-prescription medicine for the pain or to ask for prescription pain medicine, if needed.

A small amount of bleeding from the biopsy site may be expected. Ask your doctor how much drainage to expect.

If biopsy procedure other than listed above is performed, the investigator will review the procedure and discuss with you regarding potential risks.

Serious problems from a liver biopsy are rare. Problems may include (but may not be limited to):

- Bleeding, which may need blood transfusions or surgery to correct,
- A collapsed lung,
- Injury to the intestines, blood vessels, nerves, gallbladder or kidney,
- Infection in the belly.

Electrocardiogram Risks
Electrocardiograms (ECGs) will be done during this research study. ECG is a test that records the heart's electrical activity. During an ECG, electrode patches/sensors are applied to the chest area, as well as your arms and legs. You may experience temporary discomfort (pulling on the skin/skin hair) during removal of the sensors. You may also develop some minor skin irritation from the ECG patch adhesive.

Blood Draw Risks
You might feel pain or be light-headed from this. You may have the following at the site of the needle stick when blood is drawn:

- Additional bleeding at the site of the blood draw
- Temporary discomfort
- Bruising
- Swelling
- Infection (rarely)

Fasting Risks
You will be asked to fast for 8 hours before some of your visits to the study center. Fasting for 8 hours may cause dizziness, headache, stomach discomfort, or fainting.

Incidental Findings
It is possible that the study procedures could detect a possible medical problem that is unrelated to the purpose of this research study that was previously unknown to you. If the research procedures uncover findings that may be important for you to know about, such as the possibility of a previously unknown medical condition, you will be informed by a member of the study staff. Or, you may authorize the release and communication of the findings to your primary physician. These findings may require additional testing or treatment. The cost of any additional tests or related treatment will be your responsibility.

Fertility and Pregnancy Risks

Women of Childbearing Potential
If you are a female, the effect of CVC on your ability to become pregnant is not known. In addition, the effect of CVC on an unborn baby or a nursing child is not known. Therefore, if you are pregnant, planning to become pregnant or are breastfeeding a child, you cannot participate in this research study. You must confirm that, to the best of your knowledge, you are not pregnant, and that you do not intend to become pregnant during the research study.

If you are a female of childbearing potential (i.e. not post-menopausal or surgically sterilized), your study doctor must confirm that you are not pregnant by performing a pregnancy test before study entry. Additional pregnancy testing will be done during the treatment period per the study schedule and after the last dose of study treatment and as required locally. Blood or urine pregnancy test will also be done when you miss your period or when pregnancy is suspected.

To be considered a woman of non-child bearing potential you should have had a hysterectomy, or had your tubes and ovaries removed or menopausal. If you are post-menopausal, you should not have had menses in the past 12 months and may be required to have a simple blood test to confirm. If you are a postmenopausal woman, blood will be drawn to test your follicle stimulating hormone (FSH) to confirm your postmenopausal status. This is not required if you are female taking hormone replacement therapy or surgically sterile.

You should agree to use a highly effective birth control method correctly and consistently to be eligible to participate in the study and follow the birth control guidance during the study and for at least 30 days after stopping study drug.

The approved forms of birth control for this research study are:

For Men or Women Participating in the Study and his female or her male partner:

- Complete abstinence from sexual intercourse, if this is your usual and preferred lifestyle.
- Any one of the following **dual** methods of contraception:

- Condom with spermicide in conjunction with use of an IUD.
- Condom with spermicide in conjunction with use of a diaphragm.
- Condom with birth control patch or vaginal ring.
- Condom with oral, injectable, or implanted contraceptives.
- Tubal ligation or vasectomy (surgical sterilization).

In this research study, “surgical sterilization” also includes hysterectomy, bilateral salpingectomy and bilateral oophorectomy.

Women who are using estrogen-based birth control should also use another method during the research study (see above for other methods).

As part of the research study, you must agree to use an approved form of birth control. If you are not willing to use these methods of birth control during the study and for 30 days after stopping study drug, you will not be able to participate in this research study. Post-menopausal women must have not had a period for at least 12 months prior to study and will need to have a blood test to confirm they are actually post-menopausal.

If you suspect that you (or your partner) have become pregnant during the research study, you must let the study doctor know immediately. Information will be collected about your or your partner’s pregnancy until the outcome of the pregnancy is known.

Men with Partners who can get Pregnant

CVC may have an effect on the sperm or enter the semen and could be transferred to a partner in ejaculate. The effects of CVC to a partner or fetus haven't been studied.

If you are a male, the effect of CVC on your ability to make a female partner pregnant is not known.

If you are a male subject and if you have a female partner is of childbearing potential, or if you are a female of childbearing potential and your partner is male, you must consistently use an approved birth control method while in the study and for at least 30 days after stopping study drug.

If you are a male subject with a female partner of childbearing potential, you should either agree to be abstinent and agree to remain abstinent for the duration of the study and for 1 month after study completion or from last dose, or if your female partner is using a highly effective contraceptive method, you should use a condom or additional method of contraception. If you have a pregnant or breastfeeding partner you must agree to remain abstinent or use a condom. You also should refrain from donating sperm for the duration of the study and for 1 month after study completion or from last dose.

It is important for you to tell the study doctor at once if your partner becomes pregnant or you think that your partner might be pregnant while you are in the research study. If this happens, the study doctor will discuss with you what you should do. If your partner gets pregnant during the study, you may be asked questions about the pregnancy and the child. It is highly recommended that you inform your partner of your participation in the study and that contraception has been strongly recommended.

Further, you must agree that if your partner becomes pregnant while you are on the study, you will advise the study doctor. If your partner becomes pregnant, she will be asked for permission to follow the pregnancy.

POTENTIAL BENEFITS

CVC might help your NASH and liver fibrosis. But, there is no guarantee that this research study will help you. You may learn more about NASH and liver fibrosis while you are in this study. The information that is collected from the research study may help researchers find new treatments for future patients.

TREATMENT ALTERNATIVES

There is currently no approved drug for the treatment of NASH. You do not have to be in the research study to get treatment for NASH. You can choose to get treatment for the other conditions related to your NASH from your regular doctor alone instead of the study drug. Your study doctor will discuss with you the risks and benefits of other treatments.

NEW FINDINGS

If the Sponsor obtains any new information about the study drug that might change your decision to be in the research study, you will immediately be made aware of this information.

If additional procedures or tests are required for this study, you will be notified of these requirements. Before any new procedures or tests are performed, you will be asked to sign a new consent form which details the potential additional risks, discomforts and benefits.

WILL I BE PAID TO TAKE PART?

You will be paid $80.00 for each completed scheduled visit when a biopsy is not performed and $160.00 per visit when biopsy is performed. Additionally, you will be reimbursed $50.00 per visit for travel related expenses for each study visit that you complete. You will be paid at the completion of your study participation via check sent by US mail. If you require a different compensation schedule please speak to the Clinical Research Coordinator.

COST FOR PARTICIPATION

There are no anticipated costs for you to participate in the research study. The study drug will be provided to you free of charge. You will not be charged for any procedure performed for the purpose of this study.

CONFIDENTIALITY AND AUTHORIZATION TO COLLECT, USE AND DISCLOSE YOUR MEDICAL INFORMATION

In the context of the research study, the Sponsor will be responsible for all the personal data collected during the study from each participant. This responsibility is as the data controller. The data controller must ensure that all those working on the study abide by the EU Regulation on Data Protection and any additional requirements in your country law for the collection, use and processing of personal information obtained for this study.

The personal data collected will be relevant to the study. Along with medical data, other information may include your sex, age, or date of birth, ethnicity, body weight and height. The personal data will be documented in coded form (without using your name but only your allocated patient number). The data will be made available to the Sponsor of the study for the purposes of scientific evaluation.

In order to verify that the study is being conducted correctly and for safety and efficacy purposes, the contract research organization representing the Sponsor, people who work with the sponsor on the study, Government agencies, such as the FDA and the Ethics Committee will be allowed to inspect your personal records held by the study doctor. In exceptional circumstances and in accordance with the legal stipulations, the regulatory authorities may also require that personal data be made accessible. Other independent bodies may also have direct access such as a central laboratory for sample analysis and study auditors. The Sponsor will use and disclose study data (but not identify individuals) in the preparation and submission of marketing applications.

Those authorized representatives to whom personal data are disclosed are obliged to observe their duty to you and the rules of professional medical confidentiality. They are permitted to pass on the personal data of participants in coded form only and are not allowed to prepare photocopies or written copies of your medical records.

The personal data may be transferred within Europe and/or outside Europe, including to the USA. The laws about the protection of personal data in other countries may be not as strict as in this country. The personal data will be securely transferred to the USA by Sponsor's representative for central data management and will be stored in databases for the duration of the study and for the time required by Clinical Trials Law. The purpose of the transfer by Sponsor is to support regulatory submissions made by Sponsor for the study. The Sponsor and its representatives will take all reasonable steps to protect your privacy as is required by country law.

Your samples will be shipped to a central laboratory and distributed to additional testing laboratories as per the study requirements. All testing samples will be destroyed at the end of the testing process, which is estimated to take up to 15 years. Your privacy is kept as only your unique study patient number will be listed on the sample label beside the barcode number.

You may refuse to sign the consent relating to the collection and processing of personal information. However, this will prevent you from participating in the study. If you withdraw your consent to participate or for processing personal information after commencing the study, the data collected cannot be deleted due to the legal requirement to store all study data for a period of at least 15 years and because it is necessary to preserve the integrity of the research being conducted. Your right of access to the personal information collected and held and the right to correct any information that is incorrect remain and any enquiry by you in writing will be coordinated by the Sponsor as data controller.

If the results of the study are published, you will not be identified.

There is a risk of loss of confidentiality in research studies. Every effort will be made to protect you and your health information to the extent possible.

All reasonable measures to protect the confidentiality of your study records and your identity will be taken to the extent permitted by the applicable laws and/or regulations and will not be made publicly available. HIPAA Regulations or applicable state law requires that you authorize the release of any health information that may reveal your identity. The persons and entities that you are authorizing to use or disclose your individually identifiable health information may include the study doctor, the study staff, the Institution, the Sponsor and Government agencies, such as the FDA, Copernicus Group Independent Review Board (CGIRB). In order to analyze the data collected during this research study, all of the health information generated or collected about you during the study may be inspected by the study Sponsor or the authorized agents of the Sponsor, the FDA, the Department of Health and Human Services (DHHS) other government regulatory agencies from other countries (such as the US Food and Drug Administration), the study center ethics committee, IRB as well by representatives of the sponsor.

The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in these presentations. By signing this informed consent form, you are authorizing such access to your medical records. This authorization will not have expiration date.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

VOLUNTARY PARTICIPATION AND TERMINATION OF PARTICIPATION

Your participation in this research study is voluntary. You can choose not to participate in this research study either at the beginning or at any time during the research study. If you agree to take part in the study but then change your mind, you are free to withdraw your consent and stop taking part at any time without loss of benefits to which you are entitled. Your choice will not have an adverse impact on your present or future health care. There will be no penalty or loss of benefits to which you are otherwise entitled. To ensure your safety, you will be asked to undergo a final evaluation visit. If you wish to withdraw from the research study, you should contact your study doctor or study personnel at the number found on the first page of this form.

You may also revoke the authorization to use or disclose personal information about your health. If you choose to withdraw your authorization, you must notify the study doctor in writing.

The study doctor will still be able to use the information collected about you prior to your withdrawal from the study. Information that has already been sent to the study Sponsor cannot be withdrawn.

Your participation in this study may be discontinued without your consent by the investigator or the sponsoring company if you fail to follow the investigator's instructions. You may also be withdrawn from the study if, in the investigator's opinion, the study drug is ineffective, harmful, or has medically unacceptable side effects, or for other reasons at the discretion of the Sponsor or investigator. If you are withdrawn from the study, you will be asked to have the appropriate medical tests and follow-up to evaluate your health and safety.

COULD I BE WITHDRAWN FROM THE STUDY?
Your doctor or the sponsor may withdraw you from the study without your consent for the following reasons:

- if you have a side effect from the study drug(s),
- if you need a treatment not allowed in this study,
- if you do not follow the study procedures as instructed,
- if you become pregnant, or
- if the study is canceled by the FDA or the sponsor.

The sponsor, the FDA, or the IRB may decide to stop the study at any time.

IN CASE OF STUDY-RELATED INJURY
If you believe you have been injured by participating in this study, the study doctor will arrange treatment for you or refer you for treatment.

If you suffer any injury as a direct result of the study procedures or the study drug, and not due to the natural course of any underlying disease or the treatment process for such condition, and you have commercial or other non-governmental insurance benefits, reimbursement for all related costs of care will be sought first from your insurer or managed care plan.

If costs of care related to such an injury are not covered by your insurer or managed care plan, or are covered by a Federal or State benefits program, the Sponsor will pay for reasonable and necessary medical expenses that are a direct result of the study procedures or the study drug, and not due to the natural course of any underlying disease or the treatment process for such condition. The Sponsor will not pay for such expenses if you did not follow the directions of the study doctor and/or the study staff.

To pay these medical expenses, the Sponsor will need to know some information about you like your name, date of birth, and social security number or Medicare Health Insurance Claim Number. This is because the Sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare. The Sponsor will not use this information for any other purpose. Neither the Sponsor nor the study

doctor will provide other compensation in the event of an injury. However, 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 research.

You do not give up any legal rights by signing this consent form.

EMERGENCY AND IRB CONTACT

If you have any questions, concerns, or complaints about this research study, you may call the study site. The study doctor's contact information can be found on page 1 of this document.

If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

Copernicus Group Independent Review Board (CGIRB)
Telephone: 888-303-2224
Email: irb@cgirb.com

CGIRB is a group of people who perform independent review of research.

CGIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact CGIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Please visit the Copernicus Group IRB website www.cgirb.com for more information about research studies and the role of a research subject.

REGULAR DOCTOR OR SPECIALIST NOTIFICATION OPTION

Please indicate below whether you want us to notify your regular doctor or specialist of your participation in this study.

☐ Yes, I want the study doctor to inform my regular doctor/specialist of my participation in this study:

_____ _____
Name of Doctor Phone

☐ No, I do not want the study doctor to inform my regular doctor/specialist of my participation in this study.

☐ I do not have a regular doctor/specialist.

☐ The study doctor is my regular doctor/specialist.

SUBJECT'S STATEMENT OF CONSENT

AURORA: A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Cenicriviroc for the Treatment of Liver Fibrosis in Adult Subjects with Nonalcoholic Steatohepatitis

Do not sign this consent form unless you have had a chance to ask questions and have received answers to all of your questions. If you agree to participate in the study, please sign this document and you will receive a copy to take home with you.

Your signature indicates:

- that you have read and understood the above information
- that you have discussed this study with the person obtaining consent
- that you have had the opportunity to ask any questions you may have
- that all of your questions have been answered to your satisfaction
- that you have decided to take part voluntarily (of your free will) based on the information provided
- that you agree that your Study Data, including health and race data, can be used and transferred outside of your home country for the purposes set out in this form.
- that you agree that your blood samples will be stored for safety testing or exploratory analyses
- that a signed and dated copy of this form has been given to you.

Your signature also indicates that you authorize the release of your medical records related to this study to the Sponsor, vendor, CRO, IRB, the FDA, and other regulatory agencies for purposes related to the study or the study drug.

Signature of Subject Date of Signature

Printed Name of Subject

The information about the study was described to the subject in language he/she understood.

Signature of Person Obtaining Consent Date of Signature

Printed Name of Person Obtaining Consent

CONSENT FORM FOR RESEARCH ON BIOLOGICAL SAMPLES

AURORA: A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Cenicriviroc for the Treatment of Liver Fibrosis in Adult Subjects with Nonalcoholic Steatohepatitis

Consent to Use Samples for Pharmacokinetic Analysis		Subject to initial
• I consent to samples during Part 1 and Part 2, as applicable, to be taken for Pharmacokinetic analysis	Yes ☐ No ☐	
• I have been informed that if I do not consent to provide additional samples, I can still participate in the main study.	Yes ☐ No ☐	

By signing below, I confirm I have read and have expressed my choice. I understand I can change my mind at any time, for any reason.

Signature of Subject Date of Signature

Printed Name of Subject

The information about the study was described to the subject in language he/she understood.

Signature of Person Obtaining Consent Date of Signature

Printed Name of Person Obtaining Consent

AUTHORIZATION (PERMISSION) TO USE AND DISCLOSE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES

Purpose of this Form

State and federal privacy laws protect the privacy of your health information. These include the right to know who will receive the information and how it will be used. Under the law, health information that includes identifiable patient information may not be used for research purposes unless you give written permission in advance. You do not have to sign this Authorization. If you do not sign this Authorization, you will not be allowed to take part in this research study. Your decision not to sign this Authorization will not affect any other treatment, healthcare, enrollment in health plans or eligibility for benefits.

Your health information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What health information will be obtained, used or disclosed?

Health information related to this study may be used or disclosed in connection with this research study. Health information shall mean information contained in your medical or other healthcare records. Health information may include, protected health information that can identify you. For example, we may collect your name, mailing/email address, phone number, birthdate, medical record number and social security number, however, all information released outside of the clinic will be coded and your identity will not be disclosed. Health information collected in connection with this research study may also be found in the following:

- Pathology reports
- Progress notes
- Personal questions
- Health and medication questions
- Vital signs measurement
- History and Physical exams
- Laboratory Reports
- Menstrual or menopausal status
- Pregnancy tests
- All research related information and study data

Who may use and disclose your health information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Principal Investigator,
- Tobira Therapeutics Inc., a subsidiary of Allergan plc and any other affiliates, subsidiaries, agents, contractors and related companies of Tobira Therapeutics Inc. a subsidiary of Allergan plc, as necessary
- Study doctor's Research staff

Who may receive or use the information?
The parties listed in Section C above may disclose your health information to the following persons and organizations in connection with this research study:

- Sponsor and/or its representatives, including affiliates, agents and contractors "Tobira Therapeutics Inc., a subsidiary of Allergan plc"
- Contract Research Organization (CRO);
- Business associates working with the Sponsor on this research study (e.g. laboratories);
- Copernicus Group Independent Review Board (CGIRB) The Office for Human Research Protections in the US Department of Health and Human Services (DHHS);
- Federal and regulatory authorities (e.g. United States Food and Drug Administration (FDA), including the FDA and other federal regulatory agencies as required, including those outside of the United States.

Why will this information be used and/or given to others?
The sponsor and the groups above will use your health information:

- to complete this research
- to evaluate the results of the study
- to check that the study is being done properly
- to obtain marketing approval for new products resulting from this research

Is my health information protected after it has been given to others?
Your health information may be further shared by the groups above. If shared by them, the information will no longer be covered by this Authorization. These groups are committed to keeping your health information confidential.

What is the purpose of this research study and how will my health information be utilized in the study?
This study is being conducted to identify:

- How effective CVC is when compared to a placebo for the treatment of liver fibrosis in patients with NASH. A placebo looks like the study drug but does not contain the study drug's active ingredient.
- How safe CVC is when compared to a placebo.

This is a research study conducted to identify whether the study drug called cenicriviroc (CVC) is safe and effective for the treatment of liver fibrosis in people who have NASH. Based on your medical history, you may be eligible as a subject with NASH, with suspected or diagnosed liver fibrosis. Your information about you and your health, and information that may identify you is being collected for the purposes of the research study. The Sponsor will use your information to check the safety and results of the research study and to seek government approval of the study drug in order to market the study drug.

Regulatory authorities and the IRB may also review and copy your information to make sure that the research study is done properly or for other purposes required by law.

The results of this research study may also be presented at scientific or medical meetings or published in scientific journals. Your identity will not be disclosed in any of these meetings or publications.

Your information may also be used along with the medical information of others to make and keep a research database. The database will be used for follow-up or future research and/or statistical purposes regarding medical conditions such as yours.

Your information may also be transferred to other countries which may have different privacy laws.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to take part in this research study and you will not be able to receive any research-related treatment.

Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I cancel my permission or withdraw from the research study later?

You are free to withdraw or cancel your permission regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any cancellation or withdrawal, your health information will no longer be used or disclosed in the research study, except to the extent that the law allows us to continue using your information (e.g. information necessary to maintain the integrity or reliability of the research) or you have a side effect related to the study. Any revocation will not be effective to the extent that we have already taken an action in reliance on your authorization. If you wish to cancel or withdraw your permission for the research use or disclosure of your health information in this research study, you must provide written notice to the study doctor.

If you cancel or withdraw (or stop participating) from the research study and cancel and withdraw this Authorization, no new information will be collected for the research study purposes unless the information concerns an adverse event (a bad effect) related to the research study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for research study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

When will my authorization expire?

This Authorization does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely.

If the research site is located in California, Delaware, Indiana, Washington, or Wisconsin, this authorization will expire on 31Dec2060.

There is no expiration of this authorization except for research conducted in the states listed above.

Will access to my medical record be limited during the research study?

To maintain the scientific integrity of this research study, you may not have access to any health information developed as part of this study until the study is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if it was included in your official medical record). If it is necessary for your care, your health information will be provided to you or your doctor.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

AUTHORIZATION

Tobira Therapeutics Inc., a subsidiary of Allergan plc is required by law to protect your health information. By signing this document, you authorize Tobira Therapeutics Inc., a subsidiary of Allergan plc to use and/or disclose (release) your health information for this research study. Those persons who receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You acknowledge that you have received a copy of this form.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date (dd-MMM-yyyy)