INFORMED CONSENT TO TAKE PART IN A RESEARCH STUDY
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Venatorx Pharmaceuticals, Inc. / "A Phase 1, Open-label Study to Evaluate the Safety and Plasma and Intrapulmonary Pharmacokinetics of Ceftibuten and Ledaborbactam in Healthy Adult Participants"**
Protocol Number:	**VNRX-7145-105 / DMID 23-0033**
Principal Investigator: (Study Doctor)	[redacted]
Telephone:	[redacted]
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KEY INFORMATION

The purpose of this research is to test an experimental drug ledaborbactam etzadroxil (VNRX-7145) given in combination with an approved antibiotic (ceftibuten) to determine the amount of drug present in the lungs compared to the amount of drug in the blood. Experimental means that the study drug is not approved by the United States Food and Drug Administration (FDA). Ledaborbactam etzadroxil has been given to 133 research study participants.

During this study, ceftibuten-ledaborbactam etzadroxil will be given to approximately 25 people and ceftibuten alone will be given to approximately 6 people.

You will be in the study up to 37 days, including a 28-day screening window. During the study you will have study visits that include screening, study center confinement of 5 days (4 nights), and a follow-up visit 8 days later. During the study, you will receive a total of 5 doses of ceftibuten-ledaborbactam etzadroxil ([redacted]) or ceftibuten alone ([redacted]) every 12 hours as oral capsules. You will have physical examinations, blood draws, electrocardiograms (ECGs), vital signs measurements, spirometry (a test to measure lung function), and a bronchoscopy with bronchoalveolar lavage (a procedure that looks at your lungs and air passages and allows collection of a fluid sample from the lungs for testing) performed.

You will be asked to refrain from certain foods and medications as listed below and use contraception until 90 days after the last dose of study drug.

Possible risks include:

- Ceftibuten-ledaborbactam etzadroxil: headache, nausea, fatigue and more frequent bowel movements/diarrhea.
- Blood draws: pain and or bruising at the site
- Bronchoscopy: bleeding, infection, a hole in the airway, irritation of the airways, irritation of the vocal cords, vocal cord spasm, spasm of the larynx, spasm of the bronchial tubes, air in the space between the lung covering that causes the lung to collapse, pneumonia, fainting, and nosebleeds. Extremely rare complications include respiratory failure and death.

Details on what type of side effects are more common when taking these study drugs are described in the "What are the potential risks of being in the study?" section of this document.

You will not benefit from being in this study. You decide if you want to take part or not take part in this study. No matter what you decide to do, your decision will not affect the medical care or benefits to which you are otherwise entitled.

The remaining information in this document will describe more about the research study. Members of the study staff will talk with you about the information in this document. You are encouraged to ask any questions and discuss this study with clinic staff, family, friends, and personal health care providers to help you make your decision.

SPONSOR

The pharmaceutical company sponsoring this study is Venatorx Pharmaceuticals, Inc (Malvern, PA). This study center is being paid by Venatorx Pharmaceuticals, Inc. to conduct this study.

What is the purpose of this form?

You are being asked to participate in the above-named research study. Before agreeing to participate in this research study, it is important that you carefully read and understand this informed consent document and ask any questions you may have. You are free to decide if you want to take part in this study or not.

- Before a new medication can be prescribed by doctors, it must be tested. This is to ensure it is safe and works as expected.
- Before you decide if you want to take part in this study, it is important that you understand:
  - Why this study is being done.
  - The possible harms and benefits.
  - What will be required of you if you take part in the study.
- Deciding to take part is referred to as giving your 'informed consent'. This document will help you make that decision. Please take your time to read the

information carefully. You may wish to talk to your family, friends, doctor, or study staff before deciding.
- If you decide you would like to take part in this study, you will need to fill out the 'Consent' portion located at the end of this document.

This study has been reviewed by [redacted] Institutional Review Board (IRB), an organization that is responsible for protecting the rights and safety of participants who take part in research studies. Although [redacted] has reviewed the information provided in this informed consent form and has granted approval for the study doctor to conduct the study, this does not mean [redacted] has approved your participation in the study.

Please read the remainder of this document as it provides additional information about the study.

Why is this study being done?
The resistance of bacteria to antibiotics is an increasing problem. Bacteria produce proteins that break down antibiotics and make the antibiotic no longer effective. Ledaborbactam etzadroxil is a new study drug that may potentially be used to stop the breakdown of the antibiotic by the bacteria. Ceftibuten is an approved antibiotic for the indications of some bacterial infections (for example, chronic b[redacted] otitis media, pharyngitis, and tonsilitis). The Sponsor is developing ledaborbactam etzadroxil to be used in combination with ceftibuten.

In this study, we are studying how quickly and to what extent ceftibuten-ledaborbactam etzadroxil is absorbed, transported, and eliminated from the body (blood and lungs) of the participants. We will also investigate the safety of the combination of ceftibuten-ledaborbactam etzadroxil in healthy adult participants.

What do you need to know about this study?
This study is being conducted at single study center in the United States. This study will enroll approximately 31 participants.

To participate in this study, you must be a healthy adult male or female between the ages of 18-55 years old, inclusive, at the time of screening. Participants must also meet a list of criteria for the study. Even though you may meet all the criteria for participation, it is possible that you will not be enrolled in this study.

The study staff will review your medical history, including alcohol and tobacco use, and other information that may impact your participation in this study.

If there are any changes to your health, please tell the study staff right away. If you don't tell the study staff of any changes, you may no longer qualify for the study or it might not be safe for you to participate.

What will happen during this study?
You may be asked to be in the study for approximately **5 weeks**. This includes:

- Screening period (questions and tests to see if you are eligible for the study) that will occur up to 28 days before the beginning of the study period. You will not be confined to the study center during the screening period.
- Clinic study dosing period (if you are eligible and enrolled after screening).
    - You will be confined to the study center for up to 5 days and 4 nights. You will receive 5 doses of study drug during this time.
- You will be discharged from the study center on the fifth day of your confinement (Day 4).
- A follow-up visit after discharge from the study center on Day 8.

You will be asked to come to the study center about 3 times to complete the study. However, you may need to come to the study center for additional visits at the discretion of the study doctor if you have had a change in your health that needs to be monitored or if additional assessments such as needing laboratory samples collected or having vital signs or physical exams performed.

DOSING AND PROCEDURES

You will receive a total of five oral doses of ceftibuten ([redacted] capsules) with or without ledaborbactam etzadroxil ([redacted] capsules), with doses given every 12 hours. Group 1 will receive ceftibuten-ledaborbactam etzadroxil and Group 2 will receive ceftibuten alone.

Each dose will be administered with approximately one cup of room-temperature water.

One of the study staff will visually inspect your hands and mouth after the study drug intake. This it to confirm that you have taken and swallowed all of the study drug.

STUDY PROCEDURES

Below is a list of explanations for the procedures that will be done during the study. Not all procedures will be done at every visit. Some of these procedures may be done if you discontinue from the study early. The study doctor or study staff will be available to discuss these with you in more detail and answer any questions that you may have.

Procedure	What is it?	When is it done?
Informed Consent	Before entering the study, you will be asked to read, sign, and date this consent form. If you decide to be in the study, the screening evaluation process will begin.	Screening visit
Demographic Information	Your demographic information (age, sex, race, ethnicity, birthdate, etc.) will be recorded.	Screening visit Day -1 Check-in

Procedure	What is it?	When is it done?
Spirometry	A spirometry test will be performed at screening to evaluate your lung function. During the test, you will be sitting upright. A clip will be placed on your nose and you will be given a plastic mouthpiece connected to the spirometry machine. You will place your lips tightly around the mouthpiece and be asked to take in as big and deep a breath as possible and then blow out as hard and fast as you can.	Screening visit
Review medical history	We will ask you about your wellbeing and details about your health, including the diseases you have been diagnosed in the past, your current health, and your bowel movement habits. Your medical (including drug and alcohol use, menstrual history, and recent sexual activity) and surgical history (including surgical sterilization, if applicable) will be recorded.	Screening visit Day -1 Check-in
Review of current medications	Any prescription or non-prescription medications will be documented.	Screening visit Day -1 Check-in Study Treatment Phase Early Termination Follow-up
Physical examinations	The study doctor or study staff will perform a physical examination. The study doctor will listen to your heart and lungs.	Screening visit Day -1 Check-in Study Treatment Phase Early Termination Follow-up
Body weight and height	Your height and weight will be measured at screening. Your weight will be measured again on Day -1.	Screening visit Day -1 Check-in

Procedure	**What is it?**	**When is it done?**
Vital signs	Your blood pressure, heart rate, number of breaths per minute, and body temperature will be measured regularly, after you have been lying down on your back for at least 5 minutes.	Screening visit Day -1 Check-in Study Treatment Phase Early Termination Follow-up
Bowel Movement Assessment	The frequency and consistency of your bowel movements will be recorded when you are confined to the study center. We will ask you to record your bowel movements using a diary after you are discharged from the study center until you return for the Follow-up visit.	Day -1 Check-in Study Treatment Phase Early Termination Follow-up
ECG (Electrocardiogram)	An ECG (which measures how your heart is beating) will be performed at screening and on Day -1. Sticky patches will be applied to your chest and extremities. Male participants may have to shave their chest hair so that the patches will stick to their skin. Female participants may need to remove bras for the ECG. It is recommended that females wear a wireless sports bra for all visits. The ECG will be performed after you have been lying down on your back for at least 5 minutes.	Screening visit Day -1 Check-in
Bronchoscopy, bronchoalveolar lavage, and fluid sample collection	A thin tube with a camera will be inserted through your nose or mouth down your throat and into your lungs. A small amount of salt and water solution (4 instillations of approximately 3 tbsp) will then be inserted through the tube and then suctioned to wash your airway and to allow collection of a liquid sample to evaluate the amount of ledaborbactam etzadroxil and ceftibuten in your lungs.	Study Treatment Phase

Procedure	What is it?	When is it done?
Urine sample collection	Your urine will be collected several times (collection of urine may be observed). Urine samples will be used for: • Routine urine tests to check if there are side effects that change your urine • Pregnancy testing (if you are a female)	Screening visit Day -1 Check-in Study Treatment Phase Early Termination Follow-up/
Blood sampling, needle or cannula/IV (tube in an arm vein)	Blood will be drawn from a vein using either a needle or an IV catheter that is left in your arm. The total amount of blood drawn will be approximately: 226 mL (15 tablespoons) (Group 1) or 194 mL (13 tablespoons) (Group 2). Blood will be drawn for: • Routine laboratory tests to check if there are side effects that change your laboratory test values • Pregnancy testing (if you are a female of childbearing potential) • Analysis of the amount of ledaborbactam etzadroxil and ceftibuten absorbed into your bloodstream	Screening visit Day -1 Check-in Study Treatment Phase Early Termination Follow up
Drug and alcohol screen	• Your urine will be used to check for cotinine and drugs of abuse (including cannabinoids, amphetamine, opiates, methadone, cocaine, benzodiazepine, barbiturate, and nicotine). • You will undergo an alcohol breath test to check for alcohol usage.	Screening visit Day -1 Check-in
Review of side effects and medications	At each visit, the study doctor and study staff will ask about any changes to your health and medications.	Screening visit Day -1 Check-in Study Treatment Phase Early Termination Follow-up

Screening does not guarantee entry into the study. Entry into the study will depend upon the results of your screening evaluation and the opinion of the study doctor.

You may be selected as a backup participant for the study treatment visit. Backup participants must follow all the study restrictions and be ready to participate in the study just as all other eligible participants. Backup participants will replace participants who are not eligible to receive the study drug or who do not show up for the study treatment visit.

You will return to the study center for the study treatment period on Day -1.

You will receive the study drug treatment and have study procedures performed as outlined in the "Dosing and Procedures" section of this consent form.

Once the study doctor thinks that you are medically stable, you will be discharged from the study center on Day 4.

You will be asked to return for a follow-up visit on Day 8.

Once the above procedures have been completed, your participation in the study will end unless you experience a change in your health that needs to be monitored.

STUDY RESTRICTIONS

In order to be in this study, you must agree to refrain from the substances and activities listed in the chart below for the specified timeframes.

Medication, Substance or Activity	**Timeframe:**
Food and drinks	• No food or drinks (water is allowed) from 2 hours prior until 2 hours after each administration of the study drug. • No water 1 hour prior to and until 1 hour after each administration of the study drug (excluding the amount of water consumed at dosing). • No food, drinks, or water within 4 hours before and 2 hours after bronchoscopy.
Consumption of food containing poppy seeds, grapefruit, or Seville oranges	Within 48 hours prior to admission to the study center (Day -1) until the end of the study (Day 8).
Consumption of alcohol	Within 48 hours prior to admission to the study center (Day -1) until the end of the study (Day 8).
Use of tobacco, nicotine, and marijuana-containing products	Within 14 days prior to screening and until the end of the study (Day 8).

Medication, Substance or Activity	**Timeframe:**
Strenuous physical activity (for example, contact sports, activities which make you out of breath, cause muscular pain, or make you sweat) and sunbathing	Within 48 hours prior to admission to the study center (Day -1) until the end of the study (Day 8).
Use of any prescription medications/products other than hormonal contraceptives	Within 14 days prior to the first dose of study drug (Day 1). Exception can be made for certain type of medication such as cream or eye drops at the discretion of the study doctor.
Use of any over-the-counter medication, vitamin preparations and other food supplements, or herbal medications	Within 14 days prior to the first dose (Day 1) and throughout the study. An exception is made for acetaminophen/Tylenol (doses less than or equal to 3g daily).
Donation of blood or plasma or loss of blood of more than 500 mL (about 2 cups)	Within 30 days prior to Check-in (Day -1)
Unprotected sex and sperm/ova donation	• For female participants: from the time of signing consent (or Day -1 check-in for ova donation only) until 90 days after the last dose. • For male participants: from the first administration of the study drug until 90 days after the last dose.
Participation in a drug or device study besides this current study	Within 30 days (90 days for a long-acting agent) prior to screening and throughout the study.

Roles and Responsibilities

As a study participant, you will have the following responsibilities:

- Follow the study guidelines as instructed by the study staff and the study doctor.
- Tell the study doctor of any illnesses or injuries, side effects, or any problems that occur during your participation in the study.
- Tell the study doctor or study staff of any new medications (prescription or over-the-counter) that you start taking after signing this consent form.
- Return to the study center as instructed by the study staff.

Note: You may be removed from the study because of inappropriate conduct, not following instructions, or violation of study protocol or the study center rules.

WHAT ARE THE POTENTIAL RISKS OF BEING IN THE STUDY?

In this study, you will receive ceftibuten-ledaborbactam etzadroxil. There is a risk of side effects from taking any drug including the study drug.

The study drug may have unknown side effects, including serious side effects. During the study, if more information becomes available regarding side effects that may be related to the study drug, the study doctor will inform you.

Many side effects go away when treatment is stopped, but in some cases, it is possible that the side effects could be serious, long-lasting, permanent, or even life-threatening. If you have a side effect during this study, the study doctor will explain to you the possible treatment options and risks associated with these treatments.

You must contact the study doctor (or staff) if you have any side effects during the study. In the case of an emergency, call the medical emergency number or go to the nearest emergency room. If you are at the study center and have a side effect, then you will be treated as needed at the site.

Ledaborbactam Etzadroxil Risks:

In the first three ledaborbactam etzadroxil studies completed by Venatorx, ledaborbactam etzadroxil alone or combined with ceftibuten was administered to 133 healthy individuals as either single ([redacted]) or multiple [redacted] doses.

The side effects that were more frequently (2% or more) observed among these 133 individuals were:

[redacted]

[redacted] As part of this clinical study, heart rate, blood

pressure, and laboratory tests related to liver function, muscle enzymes, blood clotting, and urine will be monitored.

Ledaborbactam etzadroxil has been studied in animals. In rats, no adverse effects were directly related to ledaborbactam etzadroxil, ceftibuten, or the combination of both drugs. In monkeys, changes were seen in the kidneys. No adverse effects on kidney function in humans have been identified in the completed studies. Your kidney function will be monitored in this study.

Most side effects were mild and resolved without treatment.

One additional study with participants with varying degrees of renal (kidney) impairment was also completed by Venatorx. In this study, 32 participants received single doses of [redacted] of ledaborbactam etzadroxil and [redacted] of ceftibuten, including 9 participants who had normal kidney function. Similarly to the previous studies in healthy volunteers, this single dose of the medication was well tolerated[redacted]

Ceftibuten Risks*:*

Ceftibuten was approved by the US Food and Drug Administration (FDA) in 1995 at a dose of 400 mg per day. In clinical trials in 1728 adults, ceftibuten was well tolerated at once-daily doses of 400 mg daily. The side effects were primarily related to the gastrointestinal system and resolved.

According to the FDA-approved ceftibuten U.S. package insert, the following side effects were most frequently observed (in 1 [1%] out of 100 people or more):

- Nausea (4%)
- Headache (3%)
- Diarrhea (3%)
- Upset stomach or indigestion (2%)
- Dizziness (1%)
- Abdominal pain (1%)
- Vomiting (1%)

In this study, we will use a [redacted] dose every 12 hours.

The following side effects are less frequently observed (in less than 1 [1%] out of 100 people):

- Loss of appetite
- Constipation
- Dry mouth
- Painful or difficult urination
- Belching

- Feeling tired
- Passing gas
- Fungal infection of the skin and mucous membranes
- Nasal stuffiness
- Tingling in the skin
- Itching of the skin
- Rash
- Feeling sleepy
- Sense of taste abnormal
- Hives
- Inflammation of the vagina or vaginal infection

In a ceftibuten study conducted by Venatorx, single and repeat oral doses of ceftibuten were studied in 27 healthy volunteers. Single doses of ceftibuten up to 1200 mg and multiple doses of 400 mg ceftibuten administered up to 3 times daily for 10 days for a total daily dose of 1200 mg were studied. The most common adverse events (occurring in more than one participant) observed in this study were fatigue, headache, muscle strain, and gastrointestinal adverse events including nausea, diarrhea, and abdominal pain.

All antibiotics, including ceftibuten, carry a risk of developing an infection with a bacteria called *Clostridioides difficile* (also known as “C diff”). The severity of such an infection can range from mild diarrhea (loose stools) to a life-threatening large bowel infection. In addition, the use of antibiotics could promote the growth of other bacteria and fungus.

Changes in laboratory tests related to liver function, blood clotting, and counts of blood cells can occur with ceftibuten. In healthy adult volunteers, single doses of up to 2 grams of ceftibuten (5 times the approved 400 mg dose) did not result in abnormal laboratory tests. As part of this clinical study, laboratory tests related to liver function, blood clotting, and counts of blood cells will be monitored.

Allergic Reaction Risks
All drugs, including antibiotics like ceftibuten and investigational drugs like ledaborbactam, can have side effects, including an allergic reaction, which can occur and be severe and/or life-threatening, and may require emergency care. If you have a very bad allergic reaction, you could die.

Some signs that you may be having an allergic reaction are as follows:

- 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

If you think you are having a severe allergic reaction or other serious side effects after you leave the study center, call 9-1-1 and seek medical attention immediately.

Other Potential Risks*:*

Blood Draw and IV Risks:
During your stay at the study center, you will have blood drawn from a vein using either a needle or an IV catheter that is left in your arm (a small plastic tube that is temporarily inserted into your vein with a needle). You may have an IV in place for several hours during each study treatment day. You will have approximately 226 mL (Group 1) or 194 mL (Group 2) (a little less than 1 cup) total of blood drawn during the entire study. For comparison, a standard Red Cross blood donation is about two cups of blood. You may need to return for additional unexpected visits or additional blood draws for laboratory tests if you experience a side effect.

Risks associated with drawing blood from your veins may include lightheadedness, nausea, pain, bruising, and bleeding at the site of needle puncture, inflammation of the vein, hardening of the vein, nerve damage, dizziness, fainting, and sometimes infection.

In the rare event a study center employee accidently exposes him/herself to your blood, we will draw about ½ tablespoon of blood from you and have it tested for HIV, Hepatitis B, and Hepatitis C at a local clinic. The results of the test will be shared with you, the study center employee involved, and the medical team counseling/treating the employee. The study doctor may be required by law to report the result of these tests to the local health authority.

If you have any questions about the use, storage and destruction of samples collected, ask study staff.

Bronchoscopy with bronchoalveolar lavage
During your stay in the study center, you will have a bronchoscopy with bronchoalveolar lavage performed to evaluate the amount of ledaborbactam etzadroxil and ceftibuten in your lungs.

The bronchoscopy is a procedure where a thin tube with a camera is inserted through the nose or mouth down the throat and into the lungs to view the interior of the airways. To reduce discomfort, a local numbing agent (such as lidocaine) will be sprayed into your mouth and throat. Common side effects of lidocaine are as follows: feeling hot or cold, nausea, vomiting, drowsiness, and dizziness. More serious side effects such as: seizures, cardiac effects, and changes to red blood cells occur very rarely.

The bronchoalveolar lavage involves insertion in the bronchoscopy tube of a salt and water solution to wash your airway and to allow collection of a liquid sample to evaluate the amount of study drugs in your lungs.

The possible risks associated with a bronchoscopy may include bleeding, infection, a hole in the airway, irritation of the airways, irritation of the vocal cords, vocal cord spasm, spasm of the larynx, spasm of the bronchial tubes, air in the space between the lung covering that causes the lung to collapse, pneumonia, fainting, and nosebleeds. Extremely rare complications include respiratory failure and death.

In addition to the general risks associated with the bronchoscopy, the bronchoalveolar lavage can also cause a temporary decrease in blood oxygen levels, chest pain, or a fever. These risks may be increased if you smoke or abuse drugs.

ECG Risks:
An ECG measures how your heart is beating. The test takes a few minutes and is not painful. The study staff will put electrodes (sticky patches) on your skin. The patches might cause irritation, redness, and/or itchiness. To make the patches stick, you may have to have some of the hair shaved from your skin. If chest hair is present, removing the patches can cause mild pain. Electronics (including cell phone) will not be allowed during this procedure.

Spirometry Risks:
A spirometry test is safe and commonly used to check how well your lungs work. It measures how much air you breathe in and how quickly you breathe out. The test may take 15 to 45 minutes to complete. This may be repeated up to 8 times. While typically well-tolerated by healthy individuals, there is a minimal risk of temporary dizziness, fainting, shortness of breath, fatigue, or coughing during or after the test. In rare cases, a brief increase or decrease in heart rate may occur.

Fasting Risks:
Fasting for the amount of time required in this study could cause dizziness, headache, stomach discomfort, or fainting.

Reproductive Risks:
The study drug may be a risk to an unborn child or breast-feeding baby, so it is important to read the section on “PREGNANCY RISKS/BIRTH CONTROL” carefully, whether you are a man or woman.

PREGNANCY RISKS/BIRTH CONTROL
The effects of ceftibuten/ledaborbactam etzadroxil on a fetus (unborn baby) are unknown. If you are female and become pregnant, or if you are male, and your partner becomes pregnant while in this research study, an injury to the fetus (unborn baby) that we don’t know about right now may occur.

For Females:
If you are sexually active and have not had your tubes tied (tubal occlusion/ligation) and you have a male partner that has not been confirmed as unable to have kids

(infertile/azoospermia), you will have to take effective measures to prevent any pregnancy from screening until 90 days after the last dose.

To prevent a pregnancy, you and your partner must agree to use one of the following methods of contraception:

- Hormonal contraceptives (oral, transdermal patches, vaginal or injectable),
- Intrauterine device (IUD) with or without hormones.

The above does not apply to female participants who are post-menopausal (not having menstruated for at least 1 year) or have undergone surgical sterilization. The above also does not apply to male partners who have undergone surgical sterilization (for example, vasectomy with a post-vasectomy semen analysis negative for sperm).

If you become pregnant during the study, or become pregnant within 90 days after the last dose of study drug, you should immediately tell the study doctor. The pregnancy will then be monitored more closely and reported to the sponsor of this study. If you agree, the pregnancy and its outcome, including any premature termination, will be reported to the sponsor.

For Males:
If you are sexually active and you have a female partner, you will have to take effective measures to prevent any pregnancy from first administration of the study drug until 90 days after the last dose. We do not know if the study drug will affect sperm or semen, so you should not father a child or donate sperm from the first administration of the study drug until 90 days after your last dose of the study drug.

To prevent a pregnancy and the exposure to sperm during the 90 days after receiving the study drug, you and your partner must agree to use one of the following methods of contraception:

- Male condom and spermicide (Including males with a history of vasectomy with female partners who are pregnant or breastfeeding).

The above does not apply to female partners who are post-menopausal (not having menstruated for at least 1 year) or have undergone surgical sterilization. The above also does not apply to male participants who have undergone surgical sterilization (for example, vasectomy with a post-vasectomy semen analysis negative for sperm).

If your partner becomes pregnant during the course of the study, please ask her for permission to inform the study doctor. The pregnancy will then be monitored more closely and reported to the sponsor of this study.

You will be informed of new information relating to the study.
All new findings that are discovered during this study and that may influence your decision to stay in this study will be given to you by your study doctor as it becomes available.

Does being in this study provide any benefit?
This study is for research purposes and is not designed to offer you any treatment. There is no direct benefit to you for being in this study. Information learned from the study may benefit other people in the future.

Are there any alternatives to participating in the study?
No therapeutic or other health benefits will result from participating in this study, so your only alternative is to not participate in the study.

Will it cost you anything to be in this study?
There will be no cost to you for participating in this research study.

Will you be compensated for being in this study?
You will be compensated for taking part in this research study as outlined below.

This is to compensate you for your time and inconvenience. Each portion of the research study has a dollar value assigned to it, which accumulates as you participate in this study.

Compensation Schedule:

Screening Visit (Days -21 to -2)	[redacted]	
Day -1		
Day 1		
Day 2		
Day 3		
Day 4		
Bronchoscopy Procedure (BAL) Day 3		
Follow-Up (Day 8)		
Compliance and Completion		
Total		

Total compensation for study completion will be up to [redacted] If you choose to withdraw from the research study, you will receive compensation only for the portion of the study that you have completed as outlined above.

If it is determined by the study doctor or sponsor that you should stop the study early, you will be compensated for the portion of the study you completed.

All study participants will be issued their compensation at the completion of their participation in the study. Compensation will be issued in the form of a check.

No taxes are deducted from your payment. You are responsible for paying any state, federal, or social security taxes. You will be required to provide your social security number or tax identification number, if you have one. If you receive $600 or more in one calendar year from Pulmonary Associates, PA, you will receive a 1099 tax form the

following January. Pulmonary Associates, PA reports the money you receive to the Internal Revenue Service (IRS).

If you do not have a social security number or tax identification number, the IRS requires Pulmonary Associates, PA to deduct 30% from your compensation. You will need to follow IRS guidelines to determine if you are eligible for a refund or contact a tax professional to assist you.

Do you have to be in this study?
Being in this study is voluntary. This means you can decide if you do or do not want to be in the study. If you decide to be in the study, you can stop at any time. If you decide that you no longer want to be in the study, you will be asked to complete End-of-Study Treatment procedures.

You will receive a copy of this consent form so you can read it and seek advice from others, if needed, prior to signing. If you decide to be in this study, you will be asked to sign and date this form. You will also get a copy of the signed and dated form.
You can choose not to participate in the study, or withdraw your consent to be in this study, at any time, without penalty or loss of benefits to which you are entitled.

Can you be removed from the study without your permission?
Your study doctor may end your participation in this study for any of the following reasons:

- If you develop a side effect or medical condition that may place you at risk of more complications by staying in the study or if you need a medicine not allowed in this study;
- If you become disruptive during the study;
- If you do not follow the study doctor's or study staffs' instructions;
- If you are unable to take the study drugs;
- If you are unable to keep your scheduled appointments;
- If the study is cancelled by Venatorx Pharmaceuticals, Inc., the FDA, or [redacted] IRB; the IRB is a group of individuals responsible for the review and approval of research proposed to be conducted on human participants.

Will my taking part in this study be kept confidential?
The study information will be recorded in your study records. Personal data, which may be sensitive, such as age, race/ethnicity, and health information, will be collected and processed electronically but only for research purposes in connection with this study.

Some information will also be recorded on data forms that will be sent to a data processing office and entered onto a computer.

Direct access to relevant sections of your study records will be required by Venatorx Pharmaceuticals, Inc. and their authorized representatives to check that health-related information collected for the study is correct and complete. Your study records may also be reviewed by the regulatory authorities (such as the FDA), members of the IRB and

auditors to check that the study is being carried out correctly. While every effort will be made to protect the confidentiality of your information, absolute confidentiality cannot be guaranteed.

All data collected will be identified by a code number and your identity will remain unknown. All information that leaves the study center will have your personal identifying information removed so that you cannot be identified.

Your study doctor is responsible for keeping a code list which makes it possible to link your assigned code number to your name. This will be kept in a safe place to ensure that in the case of an emergency you can be identified and contacted. The code list will be kept until 2 years after the last marketing application approval, or if not approved, 2 years following the discontinuation of the study drug for investigation, unless local regulations or institution policies require a longer retention period.
This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers can use this Certificate to legally refuse to give information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. The Certificate of Confidentiality cannot be used for information in your medical records. A Certificate of Confidentiality does not prevent disclosure of your information to the NIH, Food and Drug Administration (FDA), or federal funding agency. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you give your consent to release information to a medical care provider, an insurer, or other person to receive research information, then the researchers will not withhold that information.

If you decide to stop taking part in the study, no new data will be added to the study database following a safety visit to make sure you leave the study safely. However, we may contact you to obtain some more information about your health if you are experiencing a health problem at the time you decide to leave the study.

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.

The results of this study will be published, though you will not be identified in any report or publication. Your study doctor will be given a copy of the report or publication at the end of the study.

Future research studies
Your private information or biospecimens collected during this study will not be used or distributed for future research studies, even if identifiers are removed.

Commercial profit
Your biospecimens collected during this study may be used for commercial profit (even if identifiers are removed) and you will not share in this profit.

Clinically relevant results
Research results that are clinically relevant, including individual research results, will not be disclosed to you.

What if I have an injury during the study?
A study-related injury is any physical injury or illness caused by your taking the study drug as required under the study or having a study-required procedure, and that is not caused by your failing to follow the directions of the research study personnel. If you are injured by a medical treatment or procedure that you would have received even if you were not in the study, that is not a study-related injury. If the injury results from a pre-existing medical condition, that is not a study-related injury.

If you experience a study-related injury, the study center will provide or arrange for medical treatment. For serious, study-related injuries, please call 911.

Venatorx Pharmaceuticals, Inc. will cover reasonable, documented physician fees and medical expenses that are necessary for treatment of the study-related injury and that are not covered by your non-governmental, commercial medical and hospital insurance coverage. There are no plans to offer you any reimbursement for expenses other than medical care required for a direct injury such as lost wages, pain, or suffering. To help avoid injury, it is required that you follow all study directions provided by the study staff.

If you are insured by Medicare, any costs related to injury paid for by the sponsor must be reported to Medicare. This may require the study sponsor to have certain identifying information like your name, date of birth, and Medicare Beneficiary Identifier (MBI).

In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the Federal Government.

By signing and dating this consent form, you are not giving up any legal rights that you would otherwise have. You are not prevented from seeking to collect compensation for injury related to malpractice, negligence, or misconduct on the part of those conducting the study.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact**:**

[redacted]

Please reference the following number when contacting the Study Subject Adviser: [redacted]

LEGAL RIGHTS

You will not lose any of your legal rights to which you are otherwise entitled by signing and dating this consent form.

PARTICIPANT'S STATEMENT OF CONSENT

By signing and dating this form you are agreeing to the following:

- You have read this Informed Consent Form.
- This form describes the purpose and nature of this study.
- You have had time to review this information.
- You have been offered a chance to ask questions and received satisfactory answers, and understand the information.
- Your participation is completely voluntary. If you do not take part in the study, you will not lose any benefits.
- If you leave the study, you will not lose any benefits or legal rights.
- You will receive a copy of this signed and dated Informed Consent Form for your records.
- You agree to participate in this study.

_____	_____
Printed name of Study Participant	Date
_____	_____
Signature of Study Participant	Time
_____	_____
Printed name of person who explained this study	Date
_____	_____
Signature of person who explained this study	Time

AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

A federal regulation known as the Privacy Rule gives you certain rights concerning the privacy of your health information. The Privacy Rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Researchers covered by this rule are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify you. Under this federal law, your records cannot be used or disclosed by the study center for research purposes unless you sign and date this form. You may not take part in this study unless you sign and date this form.

By signing and dating this form, you are permitting this study center and its personnel to use Personal Health Information collected about you for the study purposes. You are also allowing the study center to share your Personal Health Information with individuals or organizations that are also involved in the study and listed below.

This section, called an “Authorization,” explains how your health information will be used and disclosed and describes your rights.

To conduct this study, the study center and its personnel may use or share your information. They may share your information with:

- The study staff, described in the Consent Form above that you must also sign and date in order to participate in this study;
- The medical staff that takes care of you and those who are part of this study;
- Any laboratories, pharmacies, or other individuals and organizations that use your Personal Health Information as part of the approved plan for this study;
- The designated Institutional Review Board such as [redacted] IRB;
- The sponsor of the study identified above;
- Others who are required by law to review quality and safety of the study including United States government agencies such as the Food and Drug Administration, the Office for Human Research Protections, and the Department of Health and Human Services; and
- Other entities that may have a need to access and use your Personal Health Information to perform functions on behalf of any of the entities listed above, for example, consultants, data storage companies, insurers, or legal advisors.

Your personal health information may be used or disclosed in order to conduct this study, as necessary for your study-related procedures or payment for such procedures, to allow the study center to conduct its normal business operations, and to ensure that information related to the study is available to the parties that need it for research purposes. The sponsor, Venatorx Pharmaceuticals, Inc., may add your information to research databases so that it can study better measures of safety and effectiveness,

study other therapies for patients, develop a better understanding of disease, or improve the efficacy of future clinical trials.

This personal health information may include, but is not limited to, your name, address, telephone number, date of birth, government-issued identification number, and medical records and charts, including the results of all tests and procedures performed during the study.

The study data that Venatorx Pharmaceuticals, Inc. requests does not include your name, address, or social security number. Instead, the study doctor uses your initials and assigns a code number to your records that are sent to Venatorx Pharmaceuticals, Inc. Your records will be assigned a code number. Your personal health information will be kept as confidential as possible under the law; however, absolute confidentiality cannot be guaranteed. However, Venatorx Pharmaceuticals, Inc. may need information that identifies you to provide payment for any research injury as discussed in the Consent form.

Your medical records will be reviewed and/or copied at the study center, Venatorx Pharmaceuticals, Inc. and/or its representatives and may be reviewed or copied by regulatory authorities or other oversight bodies, including [redacted] IRB, for this study. The purpose of these reviews is to make sure the study is being conducted properly, and that the data is being collected correctly, or for other purposes, allowed by law.

Some or all of the test results and other information will be reported to Venatorx Pharmaceuticals, Inc. Venatorx Pharmaceuticals, Inc. and its representatives will analyze this information. Their findings may be reported to the U.S. Food and Drug Administration (the FDA) or other regulatory agencies in the United States and foreign countries.

Except for the disclosures described above, they will not disclose your records to other parties. Once your health data has been shared with authorized users, it may no longer be protected by Federal privacy law.

In no event will you be identified by name in any published reports about this study or in any other scientific publications or presentations.

You have the right to request access to your personal health information from the study doctor. To ensure the scientific integrity of the study, you may not be able to review some of your records related to the study until after the study has been completed.

Your study records may be kept at the study center indefinitely following the completion of the study. You may not have the right to review your records while the study is in progress. You will be able to review your records after the study has been completed.

This Authorization does not expire. However, in California and any other state that requires an expiration date, this authorization expires 50 years from the date you sign

this authorization. You have the right to revoke this authorization at any time by giving written notice to the study doctor at the address listed on the first page of this form.

If you revoke this authorization, you will not be permitted to continue in this study. Neither the study center nor Venatorx Pharmaceuticals, Inc. will be able to use or disclose your personal health information from this study except to the extent that they have already relied on this information to conduct the study. No new personal health information will be collected, used or shared after you revoke this authorization except as required by law for safety reasons.

You have read, in a language that you understand well, the above information. The content and meaning of this information has been explained to you. You hereby voluntarily consent and offer to take part in this study and authorize the use and disclosure of your medical information.

You have not forfeited any of your legal rights by signing this authorization. You will receive a copy of the signed and dated form.

Your signature on this form will authorize (give permission for) the study center to collect and use information that can identify you.

Statement of Authorization

I have read this form, and its contents were explained. My questions have been answered. I voluntarily agree to allow the study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Study Participant

_____ _____

Signature of Study Participant Date/Time

Statement of Person Explaining Authorization

I have carefully explained to the participant the nature and purpose of this form. I have been available to answer any questions that the participant has had about this form.

Printed Name of Person Explaining Authorization

Signature of Person Explaining Authorization | Date/Time