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INTEGREVIEW IRB
SEPTEMBER 29, 2020

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF SPONSOR COMPANY:	Pfizer Inc
NUMBER AND NAME OF STUDY:	B3461095; "A PHASE 1, OPEN-LABEL, RANDOMIZED, CROSSOVER, SINGLE DOSE STUDY TO DETERMINE THE BIOEQUIVALENCE OF 12.2 MG TAFAMIDIS FREE ACID TABLET AND COMMERCIAL 20 MG TAFAMIDIS MEGLUMINE CAPSULE ADMINISTERED UNDER FASTED CONDITIONS TO HEALTHY PARTICIPANTS"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY INVESTIGATOR):	Sylvester Pawlak
TELEPHONE NUMBER 24 HOURS:	203-401-0300

INTRODUCTION

You are here today as a possible participant in a drug research study sponsored by Pfizer Inc. Whether or not you are in this study is strictly up to you. You may refuse to take part in this research study. The study staff will be available to answer questions before, during, and after the study.

The sponsoring company (the company paying for this study), Pfizer Inc, employs the study investigator conducting this study.

If you are not completely honest about your health history, you may be harmed by being in this study.

INFORMATION ABOUT THE STUDY DRUG(S)

Tafamidis will be referred to as "the study drug" in the rest of this document.

The commercial formulation is a soft gelatin capsule. It is used to treat people with transthyretin amyloid disease (TTR). TTR is a rare and fatal (deadly) form of amyloidosis. Amyloidosis is a condition where there is a build up of certain proteins in the body. This build up impairs normal function. In TTR amyloidosis, this build up is seen mostly in the heart, kidneys, nerves and intestines. It interferes with the function of these organs. Single and multiple doses of the study drug up to 80 mg are generally well tolerated. The usual dose of the study drug to treat amyloidosis is 20 mg daily. In this study, you will receive a single, oral (by mouth) 12.2 mg dose of the study in an investigational formulation and a single oral 20 mg dose of the current commercial formulation. You will receive the study drug and commercial formulation on 1 occasion at least 16 days apart.

"Investigational formulation" means that the amount of drug and the form that it is in has not been approved by the United States Food and Drug Administration (FDA).

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In this document, you may see the terms "medication", "treatment", and "treatment period". These are terms used in research studies as mentioned above. This does not mean that you will be receiving medical treatment for any condition. These terms apply to the investigational study drug and parts of the study where you will be receiving this investigational product.

The study investigator or sponsor may decide to remove you from the study at any time if it seems you are having a significant reaction to the study drug.

PURPOSE(S) OF THE STUDY

There are 2 purposes of this study:

1. To measure and compare the amount of Tafamidis in the blood after a single dose of an investigational formulation and the commercial formulation.
2. To see how the study drug is tolerated, if there are significant side effects, and how people feel after taking it.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

You will be in this study up to about 50 days. This does not include the time between screening and dosing, which can be up to 28 days.

This study involves:

- 2 dosing periods during 2 admissions
- 16 overnight stays
- 1 follow-up phone call

There will be at least 16 days between each dose.

Up to 20 healthy male and female participants will be in this study. Females must be unable to have children.

WHEN ARE YOU ELIGIBLE TO PARTICIPATE IN ANOTHER DRUG STUDY?

The decision for when you are eligible to screen for another study is based on information from the previous studies and this study. You may be eligible to dose in another study as soon as 30 days after the last dose of study drug. This information is true for most drugs. Some drugs may be present in your body longer and that may mean you may have to wait longer before entering into another study. These results are usually known after your last regularly scheduled blood sample is tested. We will always tell you this as soon as possible. We will let you know if there is a longer than usual period of time that you should not be in another drug study after this one. Our goal is to keep you from doing anything that might potentially harm you. Your safety while in these studies is our main concern.

The half-life of the study drug is 59 hours. The half-life of a drug is the time it takes for the amount of the drug in the body to decrease by half. It is expected that very little, if any, study drug will remain in your body after 12 days.

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TO BE IN THE STUDY

You cannot screen for this study if you are currently in another research study. This includes being in the follow-up visit period of another research study.

To be in this study, your medical history and screening test results must be acceptable. Also, you must meet each of the following conditions:

- You must be a healthy male or female between the ages of 18 and 55
- Females must be unable to have children and meet one of the following criteria:
  - Postmenopausal (at least 12 consecutive months without a period with no other medical cause and a blood test confirming that you are unable to have children)
  - Uterus and/or both ovaries removed (documented)
  - Both fallopian tubes removed (documented)
  - Females permanently unable to have children due to a medical cause not listed above may be allowed to participate in the study at the discretion of the study investigator
- You must have a Body Mass Index (BMI) between 17.5 and 30.5 and weigh more than 50 kg (110 lbs)
- You must have signed and dated this consent form
- You must be willing and able to comply with scheduled visits, the study plan, lab tests and other study procedures
- You must not have evidence or history of blood, kidney, glandular, lung, stomach, intestine, heart, blood vessel, liver, psychiatric, nerve, or allergic disorders (including drug allergies)
  - Untreated seasonal allergies without symptoms are allowed
- You must not have any condition that might affect your body's ability to absorb drugs (for example, gastric bypass surgery)
- You cannot be in this study if you are using/taking any drugs of abuse. A urine test will be done to check for drugs of abuse
- While on this study please do not eat anything that contains poppy seeds, as they may cause a positive drug test
- You must not have a history of excessive alcohol use or binge drinking and/or any other illicit drug use or dependence within 6 months before screening
  - Binge drinking is defined as a pattern of 5 (male) or 4 (female) or more alcoholic drinks in about 2 hours
    - You should not drink more than 14 alcoholic drinks in a week
    - A drink is defined as 8 oz. of beer, 3 oz. of wine, or 1 oz. of hard liquor
- Study staff may check your breath for the presence of alcohol. If alcohol is detected, you will not be allowed to be in this study
- You must not have taken any investigational drugs for at least 30 days before the first dose of this study
  - You must not be in another drug study at any time during this study
- Your screening blood pressure while lying down must be less than or equal to 140/90 mm Hg
- Your screening ECG (electrocardiogram that measures the electrical activity of the heart) must be normal
- You must not have any of the following laboratory test abnormalities:
  - Liver enzymes (indicate how your liver is working) greater than or equal to 1.5 times the upper limit of normal

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  - Total bilirubin greater than or equal to 1.5 times the upper limit of normal, or a direct bilirubin (for participants with Gilbert's syndrome – a harmless mild liver condition in which the liver does not properly process bilirubin) greater than the upper limit of normal
- Female participants must not be pregnant or breastfeeding
- Male participants must not have a pregnant partner
- Male participants able to father children must be able and willing to use a highly effective method of birth control (detailed later in this document) for the duration of the study through at least 28 days after the last dose of study drug
- You may not take any prescription or non-prescription drugs, or nutritional (dietary) or herbal supplements for at least 7 days before the first dose or at any time during this study
- Tylenol® (acetaminophen) may be used at doses of less than or equal to 1,000 mg a day
  - Its use must first be approved by the study investigator
  - Other non-prescription medicines that are not thought to affect your safety or the overall study results may be allowed on a case-by-case basis if first approved by the study investigator
- You may not take hormone replacement therapy within 28 days before the first dose or at any time during this study
- You must not have donated (such as at a blood bank) a unit of blood (except plasma donations) for at least 60 days before dosing
- You must not donate any blood or blood products at any time during this study and for at least 4 weeks after your last blood draw
- You must not have a history of sensitivity to heparin (a substance that stops blood from clotting) or of low platelets (cells that help with blood clotting) as a result of heparin
- You must not have a history or a current positive result for any of the following blood tests: human immunodeficiency virus (HIV), Hepatitis B surface antigen (HepBsAg), Hepatitis B core antibody (HepBcAb), or Hepatitis C antibody (HCVAb)
  - Hepatitis B vaccination is allowed
- You must be willing and able to comply with the activity and diet restrictions of the study (detailed later in this document)
- You must not be a staff member of the Clinical Research Unit (CRU) directly involved in the study, a relative of a staff member at the CRU directly involved in the study, a staff member of the CRU supervised by the study investigator, or a Pfizer employee, including family members, directly involved with the study
- You must not have any medical or psychiatric condition, including recent (within the past year) or active suicidal thoughts or behavior, or lab abnormality that could increase your risk of being in the study or receiving the study drug or in the judgment of the study investigator, make you an inappropriate participant for this study
- During the study, it is required that all male participants use condoms to prevent the potential transfer of drug through the semen to their partner beginning with the first dose of study drug through the duration of the study and for at least 28 days after the last dose, as the effects of the study drug on sperm are unknown
- Male participants must not donate sperm for the duration of the study through at least 28 days after the last dose
- You must not use tobacco or products with nicotine in an amount greater than the equivalent of 5 cigarettes per day

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WHAT WILL HAPPEN DURING THE STUDY

Screening:

Before the study starts, you will be asked to:

- Sign this consent form
- Give your race, age, gender, and ethnicity
- Review the study entry criteria
- Give your medical history
  - If you are not completely honest with your medical history, you may be harmed by being in this study
- Give your drug, alcohol, and tobacco use history
- Tell the study staff if you have taken, in the past 28 days, or are taking any over-the-counter or prescription drugs, vitamins or dietary or herbal supplements

As part of screening you must complete all of the items listed below:

- Vital signs (blood pressure and heart rate while lying down)
- Body temperature
- Height and weight
- Safety lab tests (blood and urine)
- Includes blood tests for HIV, HepBsAg, HepBcAb, and HCVAb
- Urine to test for drugs of abuse (illegal and prescription)
  - If this test is positive, you will not be allowed in the study
  - Urine collection may be monitored by a staff member of the same sex
  - You have the right to refuse to be monitored, but may be disqualified from the study
- The study investigator may decide to do an alcohol breath test
- ECG
- Complete physical exam. This may be done at screening or when you check-in for Period 1 of the study
- You will be asked "How do you feel?"
- Females who have not had a period for at least 12 consecutive months will have a blood hormone test that will confirm they cannot have children

HIV and Hepatitis Testing

As required by this study and if anyone is exposed to your blood, you will have your blood tested for the hepatitis viruses and for HIV. HIV is the virus that causes acquired immune deficiency syndrome (AIDS). If you have a positive HIV or hepatitis test, you cannot be in/remain in the study.

If the HIV test is positive, a follow-up test will be done. If the follow-up test is also positive, you will be told in private and you will also be told about counseling.

It may take weeks or months after being infected with HIV for the test to be positive. The HIV test is not always right.

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Positive results for HIV or hepatitis tests or for other infections, or possibly having certain infections, may have to be reported to the State Department of Health. If you have any questions about what information is required to be reported please ask the study investigator or study staff.

Although this testing is intended to be private, complete confidentiality cannot be guaranteed. For example, it is possible for a court of law to get health or study records without your permission.

During the Study:

During the study you will complete all of the items listed below:

- Before being brought to the second floor of the clinic for each of your in-house stay(s), your belongings will be thoroughly searched
  - You will be asked to empty your bags and set all of your belongings on the table so the staff can go through them
  - You will be asked to empty your pockets, remove your shoes and hat, if you are wearing one, and you will be patted down
  - You will be scanned with a metal detector wand
- Review the study entry criteria (Period 1 only)
- Updates to your medical history, including drug, alcohol, and tobacco use (Period 1 only)
- Updates in any medications used since screening/previous admission
- Blood and urine samples will be collected at various times throughout the study
  - The blood and urine samples will be used for safety labs
  - Any leftover blood from the samples collected for safety labs may also be used for exploratory safety biomarkers or unexpected safety findings
    - Samples to be used for this purpose will be kept for up to 1 year following completion of this study
  - Blood samples will also be used to measure the levels of study drug in your blood
    - As part of understanding how your body absorbs, distributes, and gets rid of the study drug, the samples may also be used for metabolite identification (by-product(s) or end product(s) of a drug produced as the body processes a drug) and/or evaluation of the laboratory test(s) used to measure the study drug, as well as for other internal exploratory purposes
- A sample of your blood will be collected and sent to Pfizer's biobank. Pfizer calls this sample a "Banked Biospecimen".
  - This sample will be used to study biological substances in your sample, including your genes. This will help us learn more about the study drug
  - This sample may be kept by Pfizer in a facility approved by Pfizer as long as the sample is useful for scientific research. This may be for many years (no time limit)
- Urine samples to test for drugs of abuse may be collected at various times throughout the study
  - If this test is positive, you will not be allowed to continue in the study
  - Urine collection may be monitored by a staff member of the same sex
  - You have the right to refuse to be monitored, but may be disqualified from the study
- The study investigator may decide to do an alcohol breath test at check-in and at any time during the study
- A complete physical exam will be done at study check-in, if it was not done at screening
  - A limited physical exam may be done at various times throughout the study
- The use of proper birth control will be confirmed/reviewed at each check-in, discharge from the CRU, and follow-up phone call (males)

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- Blood pressure and heart rate will be measured while you are lying down at various times throughout the study
- Body temperature will be measured at various times throughout the study
- You will be asked "How do you feel?" each day
- An intravenous (IV) catheter may be placed in a vein in one of your arms for blood collection
- ECGs (single measurements) will be done at various times throughout the study
  - It may be necessary to shave your chest so that the patches for the ECGs will stick to your skin
  - Your chest may be marked with a pen to identify the correct areas for ECG patch placement
- You will receive a follow-up phone call between 28 - 35 days after the last dose of study drug

A. Dosing Schedule:

On the dosing day of each study period you will receive your dose on an empty stomach.

Each dose will be taken with about 8 ounces of water and must be swallowed whole. We will check your mouth to make sure the study drug has been swallowed.

You will receive each of the following doses over 2 separate dosing days. You may receive these in a different order. The dosing days will be at least 16 days apart.

1. 12.2 mg tafamidis free acid tablet
2. 20 mg commercial tafamidis meglumine soft gelatin capsule

Both you and the study staff will know which of the above you are receiving.

Because this is a research study, the study drug will be given to you only during this study and not after the study is over.

B. Blood Samples:

During the study, blood samples will be taken by individual needle-sticks or by a catheter put directly into a vein in your arm. The catheter procedure consists of putting a small tube in your arm to take blood when required. Catheters are used at the judgment of the study investigator or when required by the study plan, not at the request of the participant.

There will be about 38 blood draws; 32 are to measure the amount of the study drug in your blood at various times, 5 are safety samples, and 1 is a banked biospecimen. The total amount of blood drawn during the study will be about 175 mL (which is equal to about 5.75 ounces or 3/4 cup). For comparison, the standard blood donation is about 16 ounces (two cups), once in any 56-day period.

As with all studies with blood draws, adequate rest and good eating habits are recommended.

YOUR RESPONSIBILITIES

Activity Restrictions:

- You will be confined to the CRU for 8 days during each period (2 are planned) starting with check-in
  - If a prolonged drug effect is noted and your safety is a concern, you may need to remain in the CRU longer

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  - The study investigator or study staff will decide when you can leave the CRU
- You must not do any strenuous exercise (for example, heavy lifting, weight training, calisthenics or aerobics) for at least 48 hours before each blood collection for safety labs
  - Walking at a normal pace is allowed
- You must call the CRU at the 24-hour phone number listed on the first page of this consent form for approval before taking any drugs other than the study drug(s)
  - You must report all such drugs taken during the study to the study staff
- You must not use tobacco or nicotine-containing products for at least 24 hours before each dosing and while confined to the CRU
- Lying down is not allowed for 4 hours after dosing unless needed for any study assessments

Diet Restrictions:

- You must not eat or drink anything, except water, for at least 10 hours before collection of the pre-dose blood sample for study drug and 4 hours after each dose
- You must not eat or drink anything, except water, for at least 4 hours before each safety laboratory test
- Except for 1 hour before and 1 hour after each dose, you may drink water freely
- You must not eat or drink anything with alcohol 24 hours before check-in through the collection of the last blood sample for study drug in each period
  - You must not drink red wine from 7 days before the first dose through collection of the last blood sample for study drug
- You must not eat or drink anything with caffeine from 24 hours before dosing through collection of the last blood sample for study drug in each period
  - Food and beverages with caffeine include, but are not limited to, chocolate, coffee, tea, cola, Dr. Pepper®, and Mountain Dew®
- You must not eat or drink anything containing grapefruit or grapefruit related citrus fruits (for example, Seville oranges, pomelos) including smoothies from 7 days before the first dose through collection of the last blood sample for study drug
- You must be willing to eat the food offered during the study
- Lunch will be served about 4 hours after dosing
- Dinner will be served about 9 to 10 hours after dosing
- Evening snacks may be allowed at appropriate times
- Meals will be provided as appropriate on the days you are not dosed

POSSIBLE SIDE EFFECTS AND RISKS OF THE STUDY DRUG(S) AND PROCEDURES
STUDY DRUG

All research has some risk, which may include things that could make you feel unwell or uncomfortable, or that could harm you. You might experience these risks or discomforts while taking part in this study. It is important that you tell the study team if you are feeling any of these things during the study. The study team will monitor you for risks or discomforts during the study. However, the study team does not know all of the effects that the study drug, or your participation in this study, may have on you. If you are not honest about your side effects, you may harm yourself by staying in this study. These effects might be mild or serious. In some cases, these effects might be long-lasting or permanent, and might even be life-threatening. The study team may determine that you need additional clinical procedures or medicines to

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help manage side effects. The study investigator also may decide to remove you from the study. If you take part in this study, the most likely risks or discomforts to happen to you are discussed below.

A total of 514 participants have participated in 9 studies and have been treated with the study drug and at least 330 participants have been treated with study drug for more than 18 months.

In these research participants, 377 participants had a diagnosis of transthyretin amyloid cardiomyopathy (ATTR-CM) and 137 participants had a diagnosis of transthyretin amyloid polyneuropathy (ATTR-PN).

In participants diagnosed with ATTR-CM a once daily dose of study drug tafamidis 20 mg was received by 150 subjects and a once daily dose of study drug tafamidis 80 mg was received by 227 subjects.

Although no risks considered associated with the study drug use in participants with ATTR-CM have been identified, the following are the most frequent side effects reported in participants with ATTR-CM who received the study drug in research studies.

Very Common (reported in at least 10% of participants)

- Fall
- Heart failure
- Dyspnea (shortness of breath)
- Atrial fibrillation (irregular, rapid heart rate that may cause symptoms like heart palpitations)
- Peripheral edema (fluid accumulation most commonly causing swelling of lower legs)
- Fatigue (tiredness)
- Dizziness
- Constipation

From a study in which 65 participants with ATTR-PN who received tafamidis 20 mg daily for up to 18 months, the following risks are considered associated with tafamidis use in ATTR-PN participants.

Very Common (reported in at least 10% of participants)

- Diarrhea
- Urinary tract infection - symptoms may include pain or a burning sensation when you urinate or a frequent need to urinate
- Upper abdominal pain
- Vaginal infections in women

In animal studies, the following potential risks were seen:

- Liver abnormalities
- Reproductive toxicity (abnormalities in babies exposed to study drug during pregnancy)

Due to the possible risk to an unborn child, females able to have children will not be allowed in this study.

A rare risk that could happen is a hypersensitivity reaction (like an allergic reaction). However, there have been no confirmed cases in treated participants. Changes in thyroid function, particularly in pregnant women, could also happen.

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Since the use of the tafamidis is investigational for the treatment of a certain type of heart failure (transthyretin-mediated amyloidosis). when taken alone or in combination with other medications, there may be other risks that are unknown.

All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life threatening. You should get medical help and contact the study investigator right away if you think you have any of the following symptoms of a serious allergic reaction:

- Trouble breathing
- Swelling of the face, mouth, lips, gums, tongue or neck

Other allergic reactions may include:

- Rash
- Hives
- Blisters

Any participant who experiences a significant side effect during the study may have the following additional procedures done:

- A heart monitor may be attached to the chest for a continuous reading of heart rhythm and rate
- Vital signs, including blood pressure, may be measured often
- A monitor may be placed on a finger to sense the amount of oxygen in the blood
- A catheter may be inserted into a vein in your arm so that you may be given intravenous (IV) fluids and/or medications
- Other tests or treatment may be administered as necessary for your safety including, but not limited to, additional blood draws, collection of urine, stool or other bodily fluids
    - Depending on the severity of your symptoms, you may be referred to outside medical providers or a hospital for additional evaluation and/or treatment
    - The study investigator may notify your emergency contact as appropriate in the event of an emergency while you are taking part in the study

If you are not honest about any side effects you have during the study, you may be harmed by staying in the study.

ADDITIONAL RISKS OR DISCOMFORTS

Testing of DNA and/or RNA (deoxyribonucleic acid and/or ribonucleic acid)

Genes are pieces of DNA that, through material called RNA, give instructions for building the proteins that make our bodies work. These instructions are stored in the form of a code. This is the code that you inherit from your parents and that you pass on to your children. DNA, RNA, and proteins can be studied as part of genetic research.

This study may involve studying your biology and whether a particular biological feature (including genes) is related to the effects or action of the study drug or to a disease. This may include analyzing all of your genetic information. This is called "whole genome sequencing". Sequencing a gene is like reading a book one letter at a time. This is a very thorough way to learn about genes.

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The genetic analysis is for research purposes only. It is not a medical test. This means that the medical importance of the results may not be known. They may not be related to any medical condition.

The results of tests on your sample(s) will not be given to:

- You
- The study investigator
- Any insurance company
- Your employer
- Your family
- Any physician who treats you

If you do not want genetic testing to be done on your samples, you should not agree to participate in the research described in this document.

Pfizer and researchers will put measures in place to minimize the chance that results from this research could be linked to you. There is always a chance that information from your taking part in the research may be disclosed.

Genetic Information Nondiscrimination Act (GINA)

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not ask for your genetic information that we get from this research
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment

You should know that this Federal law does not protect you from genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Blood Samples and IV catheter (if used):

Possible side effects of having your blood drawn or an IV catheter inserted into a vein in your arm include:

- Bleeding at the site of the needle puncture
- Bruising
- Feeling faint
- Rarely infection or blood clot
- Redness of the vein and/or pain
- Nerve damage

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If you feel faint, tell one of the study staff immediately.

Electrocardiogram:

Possible side effects from having an electrocardiogram include:

- Irritation or rash from the adhesive on the patches

A rash may result in a long lasting discoloration of your skin. If it is necessary to shave the area where the patches need to be, irritation from shaving may occur. The sticky pads used may be cold when applied and sometimes cause some discomfort such as redness or itching.

It is important that you report all symptoms and side effects that you experience as soon as they occur, whether or not you think they are caused by the study drug. The phone numbers for the study team are on the first page of this document.

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

The effects of the study drug on the following are not known:

- Pregnancy
- Unborn child
- Breastfeeding child

Birth control methods, even when used properly are not perfect. If your partner becomes pregnant during the study, or you want to stop your required birth control during the study, you should tell the study investigator immediately. You may be withdrawn from the study if you stop using birth control.

Females

Women in this study should not be able to get pregnant. Women who can be in this study could include:

- Women who have had no period for at least 12 consecutive months with no other medical cause plus have a blood hormone level confirming that you cannot get pregnant
- Women who have had their uterus and /or both ovaries removed (documented)
- Both fallopian tubes removed (documented)
- Females permanently unable to have children due to a medical cause not listed above may be allowed to participate in the study at the discretion of the study investigator

Males

You must agree to the following during the study and for at least **28 days** after the last dose of study drug:

- Refrain from donating sperm

PLUS, either

- Be abstinent from heterosexual intercourse with a female able to have children as your preferred and usual lifestyle (abstinent on a long-term and persistent basis) and agree to remain abstinent

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OR

Must agree to use a male condom when engaging in any activity that allows for the passage of ejaculate to another person.

In addition to male condom use, a highly effective method of birth control may be considered for female partners able to have children. Highly effective methods of birth control include:

- Implantable hormone birth control
- Intrauterine device (IUD)
- Intrauterine hormone-releasing system (IUS)
- Bilateral tubal occlusion (both tubes blocked) which includes bilateral tubal ligation (both tubes tied)
- Partner has a vasectomy (absence of sperm confirmed)

Even if you use birth control during the study, there is a chance you or your partner could become pregnant. If you or your partner are pregnant or become pregnant during the study, the study drug/device or procedure may involve unforeseeable risks to the unborn baby.

A pregnancy test is not always right, especially in the early stages of pregnancy.

You cannot be in the study if you are breastfeeding. It is not known whether the study drug/device can be given to breast fed babies. Therefore, if you are breastfeeding a child you cannot participate in the study.

Pregnancy Follow Up:

If your partner becomes pregnant during the study or within 28 days after you have stopped taking the study drug, please tell the study investigator immediately. Please also tell the doctor who will be taking care of your partner during the pregnancy that you took part in this study. The study investigator will ask if your partner or her pregnancy doctor is willing to provide updates on the progress of the pregnancy and its outcome. If your partner agrees, this information will be provided to the study investigator for safety follow-up.

POSSIBLE BENEFITS OF THE STUDY

You will get no medical benefit from being in the study. Information from this study may benefit persons with Amyloidosis in the future.

ALTERNATIVES TO PARTICIPATING IN THIS STUDY

Since this study is for research only, the only other choice would be not to be in the study.

RELEASE OF YOUR MEDICAL RECORDS AND PRIVACY (CONFIDENTIALITY)

The clinic staff will record:

- Your medical history
- The dose(s) you receive
- The results of exams and tests done during the study

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Your name will not appear in the study data. Instead you will be identified by a participant-identification number. The information from the study data may be shared with others.

Your clinic records may include:

- Health information about you
- Documents that directly identify you

People from the groups listed below may need to look at your clinic records to make sure that the study information is correct and that the study was run as it should have been.

These reviews may take place during the study or after the study is over.

Your study information may be shared with the following people or groups:

- Pfizer Inc or its representatives, including its auditors and companies it hires to provide study-related services
- IntegReview IRB, the IRB that approved this study, and any other committees responsible for overseeing the research
- Researchers who are conducting this study at other study centers
- Government health agencies (such as the Food and Drug Administration) in the US or other countries
- Accrediting agencies

People from these groups may get information from your study data. Or, they may review your clinic records. Because of the need to share information with these people, it may not be possible to keep your identity a secret.

Pfizer will use and share your information only for research or legal reasons or to write research reports. In addition, Pfizer may:

- Capture data from electronic devices if you complete the consent process using the eConsent tablet. This information may include data about your use of the eConsent tablet such as the length of time it takes you to complete the consent process, the number of times you scroll between pages or click on the hyperlinked items, and your electronic signature.
- Look at the study data at a later date
- Add your information to information from other studies for other research reasons

However, your name will never appear in any reports, or in any future communication by Pfizer.

By signing this consent form, you agree to allow the use of your study information even after you 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.

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Please note the following information regarding the delivery of push notifications and text messages:

- The Sponsor, or a company working for the Sponsor, occasionally may send push notifications and text messages using an automated system to remind you of upcoming appointments, medication reminders and missed doses, or other study-related information
- To discontinue receiving text messages, please contact the Pfizer NHCRU at 800-254-6398
- Standard text messaging rates apply to all text messages. Message rates differ from carrier to carrier, so please contact your wireless phone provider to inquire about the details of your plan
- The contact information you have provided will be used for the sole purpose of communicating with you about the research study
- The push notifications or text messages received through this program may appear on your mobile phone screen as soon as they are received, even when the phone is locked. These messages could be seen and read by others who are near your phone when the message is received

PAYMENT FOR INJURY RELATED TO THE STUDY

If you experience a research injury, the clinic will arrange for medical treatment at no cost to you. Pfizer will cover the costs of this treatment. A research injury is any physical injury or illness caused by being in this study. There are no plans to offer you payment for such things as:

- Lost wages
- Expenses other than medical care
- Pain and suffering

To help avoid injury it is very important to follow all study directions. You can get more information about medical treatment for research injuries from the study investigator or study staff.

Remember that you must call the study investigator listed on the first page of this consent form immediately if you experience a research injury. A 24-hour answering service is available.

If you are treated for a research injury that is paid for by Pfizer, Pfizer or its representative will collect your Medicare Health Insurance Claim Number or Social Security Number to determine your Medicare status. If you are a Medicare beneficiary, Pfizer will report the payment and information about the study you are in to the Centers for Medicare & Medicaid Services (CMS), in accordance with CMS reporting requirements. Pfizer will not use this information for any other purpose.

LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

WHOM TO CONTACT

For answers to questions about this research or to report a research related injury, contact:

Sylvester Pawlak, APRN
Call the 24- hour Clinic Telephone Number
203-401-0300

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If you are unable to reach anyone at the number listed above, and you need medical attention please go to the nearest emergency room.

You will receive a card with information about this study. This information includes:

- The name or number of the study
- The clinic 24-hour phone number

You should keep this card with you in case you have a medical emergency. You can give this card to any doctor or healthcare professional, if they need more information about the research study to provide the best treatment for you.

If you do not want to talk to the study investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study participant you may contact IntegReview. IntegReview is a group of people that has reviewed this research study. The main goal of this review is to protect the rights and well-being of the human participants participating in research studies.

IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	**OR**	**Email Address:**
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway, Suite 320 Austin, Texas 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding participant safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information provided in this informed consent form and has given approval for the study investigator to do this study. This does not mean IntegReview has approved your personal participation in this study. You must consider the information in this consent form for yourself and decide whether or not you want to be in the study.

PAYMENT FOR BEING IN THE STUDY

Valid proof of a Social Security number is required before any payment is released.

The amount of payment is based on a number of things including the length of the study.

Study payments will be paid in US dollars. Compensation may be provided on a loadable debit card or by paper check. Pfizer New Haven CRU reserves the right to determine method of payment

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You will be paid $175.00 for travel expenses to and from screening. You will receive this payment within 2 weeks of screening. If we ask you to return to repeat any screening tests, you will be paid $100.00 for each trip to the clinic. If you test positive for drugs of abuse or if you leave the screening early, you will not be paid the $175.00. Travel pay for this study has been included in the participant payment. Additional travel pay is not available for this study.

Further, if you test positive for drugs of abuse:

- You will not be allowed to be in this study
- You will not be allowed to be in any future studies
- You will be removed permanently from our active database

The payment for completing the entire study will be up to $4,500.00. If you do not follow instructions your payment may be less.

If we ask you to return for additional tests, you will be paid 250.00 for each trip to the clinic. During times that you are confined to the clinic, you will not be paid more for repeat or added tests.

If you discontinue from the study, or if you are taken out of the study early, you will be paid for the time you completed. You will not be given the study completion bonus if you drop out of the study early.

If total payment by Pfizer is $600.00 or more in a calendar year, your payment will be reported to the Internal Revenue Service in accordance with Federal tax law.

Pfizer may use information resulting from the study or samples collected in the study to develop products or processes from which it may make a profit. There are no plans to pay you or provide you with any products developed from this research. Pfizer will own all products or processes that are developed using information or samples from the research study.

The decision to admit you into the study is based upon results of pre-study requirements. No one is assured a place in the study until the first dose is complete. Sufficient numbers of participants will be brought in to be sure we fill the study.

<u>Study Participants</u>

- If you successfully complete this study, the total amount you will be paid will be up to $4,500.00 ($3540.00 plus $960.00 completion bonus)
- If you do not follow instructions (including those listed in the New Haven CRU House Rules), if you are late for blood draws, or if you miss procedures, your payment will be reduced
- If you choose to leave or are withdrawn from the study before finishing all visits, your payment will be based on how much of the study you completed
    - This pay will be based on $190.00 for each overnight stay (16), $100.00 per week between periods for the washout between doses (2 weeks are planned), $250.00 for each follow up visit to the clinic (none are planned), and $100.00 per week for the time between discharge and the follow-up phone call (3 weeks)
- Partial payments are planned. Details will be given to you at screening.
- A final payment will be provided to you about 2 weeks after you finish the study

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Back-up Participants

- If you are a back-up subject who is required to stay in the CRU overnight, you will be paid $250.00 per night that you stay
- If you are not required to stay overnight, you will be paid $190.00

You will be paid a pro-rated amount based on the extent of your participation if:

- You are not able to complete the study
- You choose to leave the study
- You are withdrawn from the study early by the study investigator for non-safety related issues
- The study is stopped early
- You are qualified but not chosen to participate

YOUR DECISION TO BE IN THE STUDY

Whether you are in this study is entirely up to you. You cannot be forced to be in this study. You may not want to be in this study. You may leave the study at any time without penalty or loss of any benefits. Your future medical care will not be affected. The study investigator, Pfizer Inc, IntegReview IRB, or the FDA may take you out of the study without your permission at any time for the following reasons:

- You do not follow the instructions of the study investigator
- We find out you should not be in the study
- The study is stopped
- The study becomes harmful to your health
- You do not follow the CRU house rules

If you leave the study or if you are taken out of the study for any reason, you may be asked to return to the clinic for a final visit. You may have some end of study evaluations or tests at this visit. This is to ensure your safe exit from the study. Also, the data collected to the point of your withdrawal remains part of the study database and may not be removed.

If you are withdrawn from the study, or decide to stop the study, you can ask that any unused samples that were collected be destroyed, by contacting the study investigator. However, your samples may not be able to be destroyed because:

- They may no longer be traceable to you
- They may have already been used
- They may have been given to a third party

ADDITIONAL COSTS

There will be no charge to you for taking part in this study. The study drug, study-related procedures, and study visits will be provided at no charge to you or your insurance company.

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NEW FINDINGS

If there is new information about the safety of the study drug or changes in the study tests, we will tell you. You can then decide if you still want to be in the study.

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AGREEMENT TO BE IN THE STUDY **PIMS # _____**

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

By checking each of the following, you are agreeing that the statements below are true:

		Please Check
A.	This consent form is written in a language I understand.	
B.	I understand the information in this consent form.	
C.	I have been given enough time to ask questions and talk about the study.	
D.	All of my questions have been answered completely.	
E.	I think I have received enough information about the study.	
F.	I agree that I was not pressured by the study investigator or the study staff to be in this study.	
G.	I know that I can leave the study at any time without giving a reason and without affecting my health care.	
H.	I know that my health records from this study may be reviewed by Pfizer Inc and by government officials.	
I.	I know that I can't be in another study while I am in this study.	
J.	I have received the HIV, Hepatitis A, B, and C pamphlets and reviewed the information in them.	

IF YOU DID NOT CHECK THE BOX NEXT TO ANY OF THE ABOVE QUESTIONS, OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS, YOU SHOULD NOT SIGN THIS CONSENT FORM.

- You will get a copy of this signed and dated Informed Consent Document for your records
- You agree to participate in this study
- It is your responsibility to tell the study investigator about all changes in your physical or mental health during the study

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name or Initials of Person Explaining Informed Consent

_____
Signature or ALPHA NUMERIC CODE of Person Explaining Informed Consent Date

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL
bgb/9-3-20 ajl/9-29-20

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ADDITIONAL CONSENT REQUEST (OPTIONAL)

Use of Biological Samples for Additional Research

Pfizer would like your permission to use some or all of the samples collected in this study for additional research that may or may not be related to the study. This additional use of your samples is called "**Additional Research**."

This Additional Research is optional and you do not have to agree. You may take part in the study and contribute samples for use in the study even if you do not want your samples to be used for Additional Research.

If you decide to take part in this Additional Research, you do not have to provide any new samples. Researchers will use samples that already have been collected during the study.

There is no penalty or change to your regular medical care if you decide not to take part in this Additional Research.

1. What is the purpose of this Additional Research?

The aim of this Additional Research is to use these biological samples and the information obtained from them to understand diseases and to advance science. This includes the development of other medicines or treatments.

- This Additional Research might involve learning more about your biology. It may involve studying biological substances in your sample(s), including your genes.
- The Additional Research might include exploratory research of any disease or condition.

2. What are the possible risks of this Additional Research?

There is always a chance that information from your taking part in the Additional Research may be disclosed. Pfizer and researchers will put measures in place to minimize the chance that results from this Additional Research could be linked to you.

The testing of DNA and/or RNA risks language in the consent document for the study applies to this Additional Research.

3. What are the possible benefits of this Additional Research?

This Additional Research is for research purposes only. There is no direct benefit to you from taking part. Information from the Additional Research may help other people in the future and help in the development of new medicines or treatments.

4. What if I agree to this Additional Research and then change my mind?

You can change your mind at any time about allowing your biological samples to be used for this Additional Research. Your decision will not affect your regular medical care or any benefits to which you are entitled. Tell the study investigator if you would like to end your participation in the Additional Research.

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5. What will I have to pay for if I take part in this Additional Research?

There will be no charge to you for allowing your samples to be used for this Additional Research.

6. Will I be paid if I consent to this Additional Research?

You will not be paid for taking part in this Additional Research. Pfizer may use information from this Additional Research to develop products or processes, from which Pfizer could make a profit. There are no plans to pay you or provide you with any products developed from this Additional Research. Pfizer will own or have rights to all products or processes that are developed using information from your samples.

7. What will happen to my personal information?

All information concerning the confidentiality, use, and disclosure of your information contained in the main consent for the drug study applies to this consent as well.

Biological samples will be handled in a manner that protects your privacy and confidentiality. Biological samples will be assigned your study identification code (ID) at the site. The data generated from these biological samples will also be labeled with this ID. The key between your ID and your direct personally identifying information (for example, name, address) will be held at the study site.

It is possible that results from the Additional Research may be included in:

- Further applications to government agencies to market other medicines or devices
- Ethics committees/institutional review boards involved in research

Pfizer may share the samples and data from the samples with third parties in order to perform the Additional Research described above. The third parties may include other researchers and collaborators at institutions and companies.

8. Where can I find additional information about this Additional Research or the results of this Additional Research?

It may not be possible to link the results of the Additional Research to individuals, including you. Pfizer does not plan to give any information generated during the Additional Research to:

- You
- The study investigator
- Your personal doctor
- Your family
- Your employer
- Any insurance company

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9. Contact Information

The study team will answer your questions or concerns regarding the Additional Research. The consent document for the study provides contact information if you need to reach the study team or wish to speak with someone not involved with the Additional Research.

10. Decision to Participate in Additional Research

Below please check the box next to your choice regarding whether to take part in the Additional Research. Thank you for considering whether to participate.

☐ I agree to allow my samples to be used for Additional Research for those purposes described above.

OR

☐ I do NOT agree to allow my samples to be used for Additional Research for those purposes described above

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Signatures

- I have read and understand this Additional Consent Request.
- I have had enough time to ask questions and decide whether or not to participate.
- I understand that taking part in the optional uses described in this Additional Consent Request is voluntary.
- I do not give up any of my legal rights by signing this consent document.
- I have been told that I will receive a signed and dated copy of this document.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name or Initials of Person Explaining Informed Consent

_____
Signature or ALPHA NUMERIC CODE of Person Explaining Informed Consent Date