INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY
FOR SUPRATHERAPEUTIC EXPOSURE – PART 6 ONLY

Sponsor / Study Title:	**Pfizer Inc / "COVID-19: A MULTIPART, PHASE 1 STUDY WITH RANDOMIZED, DOUBLE-BLIND, SPONSOR-OPEN, PLACEBO-CONTROLLED, SINGLE- AND MULTIPLE-DOSE ESCALATION TO EVALUATE THE SAFETY, TOLERABILITY AND PHARMACOKINETICS OF PF-07817883 AND OPTIONAL OPEN-LABEL, RANDOMIZED STUDY TO EVALUATE RELATIVE BIOAVAILABILITY AND FOOD EFFECT OF SOLID ORAL FORMULATION AND OPTIONAL OPEN-LABEL, NON-RANDOMIZED STUDY TO EVALUATE METABOLISM AND EXCRETION OF PF-07817883 AND OPTIONAL RANDOMIZED, OPEN-LABEL STUDY TO ASSESS THE EFFECT OF PF-07817883 ON PHARMACOKINETICS OF MIDAZOLAM IN HEALTHY ADULT PARTICIPANTS"**
Protocol Number:	**C5091001**
Principal Investigator: (Study Doctor)	**Mona Shahbazi, MS, APRN**
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INTRODUCTION

You are here today as a possible participant in a drug research study sponsored by Pfizer Inc. Taking part in this study is voluntary (your choice). 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.

PURPOSE OF THE STUDY

PF-07817883 will be referred to as the "study drug" in the rest of this consent document.

The purposes in this part of this study are:

- To see how study drug is tolerated, if there are significant side effects, and how people feel after taking a supratherapeutic dose given as split doses
    - Supratherapeutic doses are dose levels higher than would normally be used to treat a medical condition

- To measure how much of the study drug is in your blood after taking a supratherapeutic dose given as a split dose
- To measure the amount of moxifloxacin in your blood after taking a single dose
- To measure the effect of 400 mg of moxifloxacin and study drug on the QTc interval (a measurement of a specific activity of the heart)

The study drug is an investigational drug being studied to treat people with SARS-CoV-2, the virus that causes COVID-19. In December 2019, COVID-19 was identified as a new, potentially fatal respiratory infection. The World Health Organization (WHO) declared COVID-19 a Public Health Emergency of International Concern on 30 January 2020, and further characterized the disease outbreak as a pandemic on 11 March 2020. COVID-19 manifests as a wide range of illnesses, from asymptomatic infection to severe pneumonia, acute respiratory distress syndrome (ARDS) and death. "Investigational" means that the drug has not been approved by the United States (U.S.) Food and Drug Administration (FDA).

Study drug and placebo will be given as a liquid which you will drink.

The placebo looks like the study drug but does not contain any active ingredients. Researchers will compare the results of taking the placebo to the results of taking the study drug to see if there are any differences.

Moxifloxacin will also be given in this part of the study. Moxifloxacin is an approved marketed drug. It is used to treat a variety of bacterial infections. It will be given as a tablet which you will swallow.

ABOUT THE STUDY

Number of Study Participants

There will be about 18 people taking part in this part of the study.

Length of Study for Participants

You will be in this part of the study for up to about 44 days. This does not include the time between screening and dosing, which can be up to 28 days.

This part of the study involves:

- 3 dosing periods during 1 continuous admission
- 20 overnight stays at the Clinical Research Unit (CRU). You will not be able to leave the CRU during that time
- 1 follow-up phone call about 4 weeks after the last dose

There will be at least 7 days between each dose.

Eligibility to Participate in Another Drug Study

Your eligibility to take part in another study depends on information from this study. You may be eligible to receive a different study drug in another study as early as 30 days after your last dose of study drug in this study. This is true for most drugs. Some drugs may stay in your body longer which means that you may have to wait longer before joining another study. These results are usually known after your last blood sample is tested. We will tell you this as soon as possible. We will also tell you 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.

Dosing Plan

The dose of the study drug that will be used to treat people is not yet known.

One group of participants is planned for this part of the study.

Dosing for this part of the study is planned as follows:

DOSING SEQUENCE	NUMBER OF PARTICIPANTS	STUDY PERIOD		
		1	2	3
1	3	STUDY TREATMENT A	STUDY TREATMENT B	STUDY TREATMENT C
2	3	STUDY TREATMENT B	STUDY TREATMENT C	STUDY TREATMENT A
3	3	STUDY TREATMENT C	STUDY TREATMENT A	STUDY TREATMENT B
4	3	STUDY TREATMENT A	STUDY TREATMENT C	STUDY TREATMENT B
5	3	STUDY TREATMENT B	STUDY TREATMENT A	STUDY TREATMENT C
6	3	STUDY TREATMENT C	STUDY TREATMENT B	STUDY TREATMENT A

Study Treatment A: 6,000 mg of study drug by mouth, given as 2 split doses of 3,000 mg each, 1 hour apart, under fasting conditions (nothing to eat or drink except water)

Study Treatment B: placebo as suspension at 0 and 1 hour, under fasting conditions

Study Treatment C: 400 mg of moxifloxacin given as a single tablet at 0 hour and placebo as suspension at 1 hour under fasting conditions

The doses of study drug and placebo that you receive are compounded in our pharmacy for use in this study. Compounded means that the ingredients are added together and mixed to make the final dose(s).

Your study treatment sequence will be randomly assigned like pulling a number out of a hat.

Both you and the study staff will not know whether you are receiving the study drug or placebo. In case of a medical emergency, the study investigator can find out what you have received.

Both you and the study staff will know when you are receiving moxifloxacin.

On Day 1 of each period you will receive a single oral dose of study drug, placebo, or moxifloxacin. You will fast overnight (nothing to eat or drink except water) for at least 10 hours before each dose.

Study drug and placebo will be given as split doses. The second split dose will be given about 1 hour after the first dose.

Each dose will be taken with water. At each dosing, the total fluid volume of the liquid doses and water will be about 8 oz. (1 cup). The dose of moxifloxacin tablet will be given with about 8 oz. of water and 1 hour later placebo suspension will be given with 8 oz of water. Liquid doses must be completely swallowed. The tablet dose must be swallowed whole. We will check your mouth after each dose to make sure the study drug, placebo, or moxifloxacin have been swallowed.

This is a research study. The study drug and moxifloxacin will be given to you only during this study and not after the study is over.

Study Process

Before any study procedures begin, you will be asked to read, sign, and date this consent document.

Screening

After you sign and date the consent document, you will begin screening. The purpose of the screening is to find out if you meet all of the requirements to take part in the study. Procedures that will be completed during the study (including screening) are described below. If you do not meet the requirements, you will not be able to take part in the study. The study investigator or study staff will explain why.

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

- Give your race, age, gender, and ethnicity
- Give your medical history
    - You must review and confirm the information in your medical history questionnaire
- Give your drug, alcohol, and tobacco use history
- Give your past and current medication and treatment history. This includes any over-the-counter or prescription drugs, such as vitamins, dietary supplements, or herbal supplements, taken in the past 28 days
- Height and weight will be measured
- Physical exam will be done
    - This may be done at screening or when you check-in for the study
- Vital signs (blood pressure, heart rate, and breathing rate) will be measured
- Electrocardiogram (ECG) will be collected. An ECG measures the electrical activity of the heart
- COVID-19 procedures:
    - You may be asked to complete a COVID-19 questionnaire
    - You may be tested for COVID-19 at each visit to the CRU
        - COVID-19 testing will be done by collection of a swab sample
    - Study staff may be wearing masks, face shields, respirator hoods, gowns, and gloves
    - You may be required to wear a mask at all times. If required, it will be provided to you
- Safety lab tests will be done from blood and urine samples. This includes:
    - Blood tests for human immunodeficiency virus (HIV), hepatitis B, and hepatitis C
    - Urine to test for drugs of abuse (illegal and prescription)
    - Blood pregnancy test for women able to have children
    - Females who have not had a period for at least 12 months in a row will have a blood hormone test to confirm they cannot have children
- The study investigator may decide to do an alcohol breath test
- The use of proper birth control will be reviewed
- You will be asked “How do you feel?”

HIV and Hepatitis Testing

HIV, hepatitis B, and hepatitis C will be tested at screening. If anyone is exposed to your blood during the study, you will have these tests done again. If you have a positive test, you cannot be in or remain in the study.

HIV is the virus that causes acquired immunodeficiency syndrome (AIDS). If your HIV test is positive, you will be told about the results.

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

Having certain infections or positive test results may have to be reported to the State Department of Health. This includes results for HIV, hepatitis, and other infections. 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 meant to be private, complete privacy 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

The events below will take place throughout the study. If you would like to know when exactly these will take place, please ask the study staff.

- You will be asked about any updates to your medical history. This includes medication, drug, alcohol, and tobacco use
- Physical exam(s) will be done
- The use of proper birth control will be confirmed/reviewed
- Vital signs will be measured. Your oral temperature may also be measured
- ECGs will be collected
    - It may be necessary to shave or trim hair on 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
- Continuous heart monitoring will be done for at least 8 hours in each period. There will also be a period of at least 2 hours where monitoring will be done before the first dosing in Period 1
    - This involves the attachment of a small box like unit (transmitter) to your chest
    - The box is attached by a few wires (similar to those of an ECG)
    - The monitor sends information about your heart's activity by a radio signal to a monitor. You may not sleep during the 2 hours of continuous monitoring done before dosing
    - You will need to stay in the procedure room for at least 4 hours after dosing while attached to the monitor
    - You will need to keep the box with you during the monitoring period
    - You will be asked to minimize activity while attached to the monitor
- 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
- The study investigator may decide to do an alcohol breath test at any time
- You will complete a COVID-19 questionnaire
- You will be tested for COVID-19
    - COVID-19 testing will be done by collection of a swab sample
- Blood and urine samples will be collected at various times throughout the study
    - Safety Labs: The blood and urine samples will be used for safety labs including the following:
        - Urine samples to test for drugs of abuse
        - Blood pregnancy test for females able to have children. Pregnancy tests may be performed at the discretion of the study investigator in all females
    - Any leftover serum (component of blood) from the safety lab samples may be stored and used to assess exploratory safety biomarkers or unexpected safety findings
        - Biomarkers are natural substances in your body that can be used to show how your body works

        - Samples to be used for this purpose will be kept for up to 1 year following completion of this study
    - Study Drug Levels: Blood samples will also be used to measure the levels of study drug and moxifloxacin
        - As part of understanding how your body absorbs, distributes, and gets rid of the study drug and moxifloxacin, the samples may also be used for the following:
            - Metabolite identification
            - Evaluate safety aspects related to any concerns during or after the study
            - Check the laboratory test which measures the study drug
            - Biomarkers
            - Other internal exploratory purposes
    - Retained Research Sample: A sample of your blood will be collected, stored, and used to learn more about the study drug
        - Biological substances in your sample, including your genes, may be studied
        - This sample may be kept by Pfizer for as long as the sample is useful for scientific research. This may be for many years (no time limit)
- You will receive a follow-up phone call about 4 weeks after the last dose
- For safety reasons, we may add procedures at any time during the study to check on your health status

Blood Draws

Blood samples will be taken by individual needlesticks, or by a catheter. A catheter is a small tube that is placed in a vein in your arm to take blood when required. Catheters are used when ordered by the study investigator or when required by the study plan. They are not used at the request of the participant.

There will be about 47 blood draws. The total amount of blood drawn during this part of the study will be about 485 mL. This is equal to about 16 oz., or 2 cups. For comparison, the standard blood donation is about 16 oz. (2 cups), once in any 56-day period.

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

Blood loss in this amount may lead to a low red blood cell count (anemia). Anemia can make you feel more tired than usual.

Possible Risks and Discomforts

Taking part in this study has some risks. The study drug or procedure(s) may make you feel unwell or uncomfortable or could harm you. If you do not understand what any of the side effects described below mean, please let us know. The study investigator or study staff will explain them to you.

It is important that you report all side effects that you have as soon as they occur. This is regardless of whether or not you believe they are caused by the study drug or your participation in this study.

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

Study Drug Risks

To date, the study drug has been administered to a small number of humans. The safety of the study drug has been studied in animals. In animal studies, no significant risks or safety events of concern were identified. The study drug did not cause adverse effects at any of the dose levels that will be used in clinical studies. Based on the studies done in animals dosed with the study drug, the potential risks include:

- Increased breathing rate
- Small decreases in heart rate
- Small increases in blood pressure
- Vomiting
- Decreased limb strength (or weakness)

There are limited clinical data from the use of the study drug in humans. As of 18 January 2023, the study drug has been given as a single dose and multiple dose (twice daily for 10 days) to a limited number of healthy volunteer participants. Although only preliminary data are available, the early data in the healthy participant study did not show significant safety concerns when participants were given up to 1500 mg of the study drug twice daily for 10 days.

During the study, you will be monitored for changes in breathing rate, heart rate, and blood pressure, changes in laboratory results, as well as for the occurrence of other symptoms or side effects. Blood and urine samples will be collected on a regular basis to measure and check for any changes in laboratory test results.

Human clinical and animal studies do not always predict the side effects that people may experience. There may be rare and unknown side effects, including reactions that may be life-threatening and could result in sickness or death.

Moxifloxacin Risks

Moxifloxacin, and other drugs in the same class, have been associated with disabling and potentially irreversible serious side effects including:

- Tendinitis and tendon rupture
- Peripheral neuropathy (damage to the nerves outside the brain and spinal cord), which can cause:
    - Weakness
    - Numbness
    - Pain
        - These usually happen in the hands and feet
- Central nervous system effects including:
    - Convulsions
    - Increased intracranial (within the skull) pressure
    - Toxic psychosis (mental disorder caused by the effect on the brain of a drug)
    - Nervousness
    - Agitation
    - Insomnia (difficulty falling and/or staying asleep)
    - Anxiety
    - Nightmares
    - Paranoia
    - Dizziness

- Headache
- Confusion
- Tremors
- Hallucinations
- Depression
- Suicidal thoughts or acts

Moxifloxacin has been shown to cause changes in the ECG. This may lead to prolonged QT interval reported on the ECG or lead to an abnormal heart rhythm. The QT interval is a measurement of a specific activity of the heart.

In this study you will be receiving a single dose of moxifloxacin.

Moxifloxacin, like nearly all antibiotics, can cause diarrhea including clostridium difficile (C.Diff) - associated diarrhea. C.Diff is an infection of the large intestine. Diarrhea can range in severity from mild to fatal colitis (inflammation of the lining of the colon).

Until you know how the study drug will affect you, you should use caution by:

- Avoiding stairs
- Not driving a car
- Not swimming or bathing in a tub
- Not working with machinery or at heights

Other Risks

Because the study drug is investigational, all of its side effects are not known. There may be rare and unknown side effects. These include reactions that may be life-threatening.

All drugs have a potential risk of an allergic reaction including moxifloxacin. If an allergic reaction is not treated quickly, it could become life-threatening. You should get medical help right away (by calling 911 or immediately going to an emergency room) if you think you have any of the following symptoms:

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

Other allergic reactions may include:

- Itchiness
- Rash
- Hives
- Blisters
- Palpitations (racing heart)
- Chest discomfort/tightness
- Muscle pains/stiffness

At times, the following may also be symptoms of an allergic reaction:

- Diarrhea
- Nausea
- Vomiting
- Abdominal pain

If a significant side effect occurs, the following may be done:

- Tests or treatment may be given as needed for your safety
- Depending on how severe your symptoms are, you may be seen by outside medical providers or a hospital. This would be for further 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

Additional Risks or Discomforts

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

Genes are pieces of DNA that give coded instructions for the body. Parts of the code are passed down from parents to their children.

The genes in your samples may be studied. This may include analyzing all of your genetic information. This is called “whole genome sequencing”. While collection of genetic information does not expose you to physical risk, collection of such information may result in a loss of your privacy if your genetic information is lost or stolen.

There is a very small chance that your genetic information could be misused by people not involved with the research, including to discriminate against you. However, steps are in place to prevent a particular result from being linked to you and to prevent unauthorized people from even knowing genetic research was done.

U.S. federal law prohibits discrimination in health insurance coverage and employment based on a person’s genetic data. However, U.S. federal law does not protect against discrimination when you are applying for:

- Life insurance
- Long term care insurance
- Disability insurance

You should talk to your physician or genetic counselor about the potential for genetic discrimination. 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

Blood Samples and IV Catheters (if used)

Possible side effects of having your blood drawn or an IV catheter inserted include:

- Bleeding at the site of the needle puncture
- Bruising
- Feeling faint
- Rarely, infection or blood clot
- Redness of the vein
- Inflammation of the vein
- Swelling
- Pain
- Nerve damage
- Vein irritation from the fluid or medication being given
- Local swelling due to IV fluid accidentally entering the tissue rather than the vein
- Scarring

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

COVID-19 Testing

Collection of a swab sample may cause:

- Discomfort
- Sneezing
- Your eyes to water
- Gagging
- Possible nosebleed

There is a risk of COVID-19 infection when you are in close contact with study staff or other study participants during the screening process and during the study. However, safety procedures will be followed during screening and the study to minimize the risk of COVID-19 transmission.

If you test positive for COVID-19 while on study, you may not be able to continue on the study. If you have a positive result it may be reported to the Connecticut State Department of Health and your local department of health. If you have any questions about what information may be reported, please ask the study investigator or study staff.

ECG and Continuous Heart Monitoring

Possible side effects from having an ECG and continuous heart monitoring 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.

Fasting

Fasting could cause symptoms such as:

- Dizziness
- Headache
- Stomach discomfort
- Fainting
- Hypoglycemia (low blood sugar)

Other

The length of time that you may be confined to the CRU may make you feel uncomfortable.

Use of Birth Control

Females

You must not be pregnant or breastfeeding. You must not donate eggs for the purpose of reproduction for the duration of the study and for at least 28 days after the last dose.

Females unable to have children

Women in this study not able to get pregnant include women who:

- Have had their uterus removed (documented)
- Have had both fallopian tubes removed (documented)
- Have had both ovaries removed (documented)
- Have not had a period for at least 12 months in a row with no other medical cause. You must have a blood hormone level confirming that you cannot get pregnant

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.

Females able to have children

If you are sexually active, you must use a highly effective method of birth control. The birth control must be used consistently and correctly from the start of dosing (earlier for hormonal birth control), during the study, and for at least 28 days after the last dose.

Highly effective methods of birth control include:

- 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)
- Sexual abstinence – defined as refraining from heterosexual intercourse and is the preferred and usual lifestyle of the participant

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

OR

Must agree to use birth control/barrier as detailed below:

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

In addition to male condom use, female partners able to have children may consider an additional highly effective method of birth control such as the methods detailed earlier in this document and the following:

- Combined (estrogen- and progestogen-containing) hormonal contraception
  - Oral*
  - Intravaginal*
  - Transdermal*
- Progestogen-containing hormonal contraception
  - Oral*
  - Injectable*
  - Implantable*
- Be abstinent from heterosexual intercourse as your preferred and usual lifestyle (abstinent on a long-term and persistent basis) and agree to remain abstinent during the entire risk period

*__Note:__ For female partners able to have children, one of the following barrier methods must be used in addition to the hormonal birth control methods detailed above:

- Male or female condom with or without spermicide
- Cervical cap, diaphragm, or sponge with spermicide
- A combination of male condom with either cervical cap, diaphragm, or sponge with spermicide (double-barrier method)

Pregnancy-Related Risks

The effects of the study drug on the following are not known and may involve unforeseeable risks:

- Sperm
- Pregnancy
- Unborn child
- Breastfeeding child

Even if you use birth control during the study, there is a chance that you or your partner could become pregnant. If you or your partner are pregnant or become pregnant during the study, the study drug or procedures may involve unforeseeable risks to the unborn child. A pregnancy test is not always right, especially in the early stages of pregnancy.

You cannot participate in this study if:

- You are currently pregnant, planning to become pregnant, or are breastfeeding a child
- You are a man whose female partner is currently pregnant or planning to become pregnant

If you want to stop your required birth control during the study, you should tell the study investigator **immediately**. You will be taken out of the study if you stop using birth control.

Pregnancy Follow-Up

If you or your partner become pregnant during the study or within 7 days after your last dose of study drug, please:

- Tell the study investigator **right away**
- Tell the health care provider(s) taking care of you/your partner during the pregnancy that you took part in this study

The study investigator will ask if you/your partner or your/her health care provider(s) are willing to provide updates on the progress of the pregnancy and its outcome. This information will be collected for safety monitoring follow-up.

PARTICIPANT RESPONSIBILITIES AND RIGHTS

Participant Responsibilities

- You must tell the study investigator if you previously took part in this study, have been in any other study in the past year, or are currently involved in any other study. This includes being in the follow-up visit period of another study
- You must agree to the scheduled visits, the study plan, lab tests, study procedures, and diet and activity restrictions (details listed later in this document)
- You must not have any significant medical or psychiatric condition, as determined by the study investigator, that may put your safety at risk or could have an effect on the study results
- You may be asked to provide documentation of your childbearing status
- You must not take any medications (including over-the-counter medications, such as medications for cold or allergies, antacids, herbal supplements, St. John's Wort, minerals, or vitamins) within 28 days before the first dose or at any time during the study
    - Before taking any drugs other than the study drugs, you must call the CRU for approval. It must first be approved by the study investigator
    - You must tell the study staff about any drugs taken during the study
- You must not take hormone replacement therapy (HRT) or some hormonal methods of birth control within 28 days before the first dose. Depo-Provera® must be discontinued at least 6 months before the first dose
- You must not have been vaccinated with a COVID-19 vaccine within 7 days before screening or admission or are scheduled for a COVID-19 vaccine at any time during your confinement at the CRU
- You must test negative for COVID-19 at the time of admission to the CRU
- You must not be at increased risk, according to the product label, if dosed with moxifloxacin (including, but not limited to participants with a history of myasthenia gravis [a disease of the immune system], tendinitis, or tendon rupture)

- You must not have a history of hypersensitivity, allergy, severe adverse drug reaction or intolerance to moxifloxacin or other drugs in the same class
    - The study investigator or a member of the study staff will review these drugs with you
- You must not take any investigational product (drug or vaccine) within 30 days before the first dose of this study
- You must not have donated blood for at least 60 days before dosing. Plasma donation may be allowed
    - You cannot donate any blood or blood products at any time during this study. Donation is not allowed for at least 4 weeks after your last blood draw
- You must not have a history of excessive alcohol use or binge drinking and/or other illicit drug use 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 a week
    - A drink is defined as 8 oz. of beer, 3 oz. of wine, or 1 oz. of hard liquor
- You must not be using/taking any drugs of abuse (such as marijuana, cocaine, opioids, etc.). Urine tests will be done to check for such drugs
    - If a test is positive, you will not be allowed in the study
    - Urine collection may be monitored by a study staff member of the same sex
    - You have the right to refuse to be monitored, but may be disqualified from the study
    - While in this study, please do not eat anything that contains poppy seeds. They may cause a positive drug test
- You must not use tobacco- or nicotine-containing products in excess of the equivalent of 5 cigarettes or 2 chews of tobacco per day
- You must not use tobacco- or nicotine-containing products for 24 hours before the first dose and while confined to the CRU
- You must not have a self-reported history or risk factors for QT prolongation or torsades de pointes (for example, organic heart disease [abnormalities of the muscle tissue of the heart], inherited long QT syndrome, myocardial ischemia [reduced ability of the heart to pump blood], heart attack, inherited deafness, family history of sudden death or long QT syndrome)
- Please let us know if you or a relative are a staff member of Pfizer. If so, you may not take part in this study if you or your relative are supervised by the study investigator or are directly involved with the study

Activity Restrictions

- You will need to stay in the CRU for 21 days starting with check-in
    - You may need to stay in the CRU longer if you experience a longer study drug effect. This is for safety reasons
    - The study investigator or study staff will decide when it is safe for you to leave the CRU
- You must not do any strenuous exercise for at least 48 hours before each blood draw for safety labs. Examples of this include heavy lifting, weight training, or aerobics
    - Walking at a normal pace is allowed
- You cannot lie down for 4 hours after dosing, unless needed for any study procedures
    - After dosing for liquid doses is defined as after the second split dose has been given
- You will be confined to the procedure room for the first 4 hours after each dose during continuous heart monitoring
- You may be asked to wear a device (similar to a wristwatch) that can be used to alert study staff in case of an emergency

Diet Restrictions

- You must not eat or drink anything (except water) for at least 10 hours before each collection of the pre-dose blood samples for study drug or moxifloxacin
    - Except for 1 hour before and 1 hour after 2nd split dose you may drink water freely
- You must not eat or drink anything (except water) for at least 4 hours before each safety laboratory test
- You must not drink red wine for 7 days before the first dose. Red wine is not allowed through the collection of the last blood sample for study drug
- You must not eat or drink anything with alcohol for 24 hours (or as stated above for red wine) before check-in. Alcohol is not allowed through the collection of the last blood sample for study drug
    - Study staff may check your breath for alcohol. If alcohol is found, you will not be allowed in the study
- You must not eat or drink anything with caffeine for 24 hours before dosing. Caffeine is not allowed through the collection of the last blood sample for study drug
    - Caffeine can be found in different foods and drinks. Some examples include chocolate, coffee, tea, cola, Dr. Pepper®, and Mountain Dew®
- You must not eat or drink anything that has grapefruit or grapefruit-related citrus fruits for 7 days before the first dose. These are not allowed through collection of the last blood sample for study drug
    - Examples of citrus fruits that are not allowed are Seville oranges and pomelos
    - Fruit juices and smoothies may also contain grapefruit or these citrus fruits
- Lunch will be provided about 4 hours after dosing
- Dinner will be provided about 9-10 hours after dosing
- Lunch and dinner after split-dosing will be timed to the second part of the split dose
- An evening snack may be allowed
- Meals (breakfast, lunch, dinner, and evening snacks) will be provided at appropriate times on all non-dosing days
- You will be restricted to drinking room temperature or warm drinks from Day 1 (before baseline ECG) until the final ECG measurements have been collected in each study period
- You must be willing to eat the food offered during the study

Possible Benefits of the Study

This study is for research purposes only. There may be no direct benefit to you from taking part. However, information learned from this study may benefit other people in the future.

Alternatives to Participating in this Study

This study is for research purposes only. Your alternative is to not take part in the study.

Confidentiality

This section describes how we will collect, use, and share your personal information.

What personal information may we collect about you during this study?

The study staff will collect information about you. This information may include:

- **Information that directly identifies you** such as your name, address, telephone number, date of birth, and Social Security Number
- **Personal information** such as your medical history, data from this study (including study results from tests and procedures), demographics (for example, age and gender) and other sensitive information that is needed for this study such as race, ethnicity, sexuality, substance use disorders, mental health disorders, diagnoses and treatment, and HIV status
- **Data from testing and analysis of biological samples** (such as blood or urine). This may also include genetic information
- **Data captured from electronic devices** if you complete the consent process using the eConsent tablet. This information may include:
    - The length of time it takes you to complete the consent process
    - The number of times you scroll between pages or click hyperlinked items
    - Your electronic signature

Who will use my personal information, how will they use it, and where will it be stored?

Any personal information collected during this study will be stored by the study staff at the CRU. The study staff must keep your personal information confidential.

Your personal information will be accessed by:

- The study investigator and other study staff members
- Pfizer and its representatives (including its affiliated companies)
- People or organizations providing services for, or collaborating with, Pfizer
- Government or regulatory authorities (including the U.S. FDA and authorities in other countries)
- Advarra Institutional Review Board (IRB), the IRB that reviewed this study and any other committees responsible for overseeing the research

The individuals and groups listed above will use your personal information to conduct this study, and to comply with legal or regulatory requirements, including to:

- Determine if you are eligible for this study
- Provide you with reimbursement, as allowed by the study, for your time, effort, and certain expenses related to your participation
- Verify that the study is conducted correctly and that study data are accurate
- Answer questions from IRB(s) or government or regulatory agencies
- Assess your use of electronic devices in the study, for example, to determine how long it takes you to complete any eConsent module used for the study and your comprehension of the eConsent process
- Contact you during and after the study (if necessary)
- Follow-up on your health status, including using publicly available sources (for example, public databases or the internet) should the study staff be unable to contact you using information held on file

- Protect your vital interests such as providing information to an emergency department of a hospital if you are being treated
- Answer your data protection requests (if any)

If you provide someone else's personal information, you should make them aware that you have provided the information to us. Examples of this information include:

- Emergency contact information
- Details of family medical history

We will only use such information in keeping with this informed consent and applicable law.

Text Messages

If you agree, the study staff, or a company working on behalf of Pfizer, may send text messages using an automated system to remind you of:

- Upcoming study appointments
- Other study-related information
  - Standard text messaging rates apply to all text messages. Message rates differ from carrier to carrier. Please contact your wireless phone provider to ask 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 study
  - The text messages received through this program may appear on your mobile phone screen as soon as they are received. This may happen 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
  - To discontinue receiving text messages, please contact the Pfizer New Haven CRU at 800-254-6398

You will be asked to make your choice at the end of this document.

What happens to my personal information that is sent outside the CRU?

Before the study staff transfers your personal information outside the CRU, the study staff will:

- Replace your name with a unique code
- Remove information that directly identifies you

This is called "**Coded Information**". The link between the code and your personal information will be kept confidential by the study staff.

Your Coded Information will be used by the following:

- Pfizer and its representatives (including its affiliated companies)
- People and/or organizations providing services to or collaborating with Pfizer
- Any organization that obtains all or part of Pfizer's business or the rights to the product under study
- Other researchers
- Advarra IRB
- Government or regulatory authorities

The above parties may use your coded information for the following purposes:

- **Conducting the study**, including:
  - Examining your response to the study drug
  - Understanding the study and the study results and learning more about COVID-19
  - Assessing the safety of the study drug
- **Complying with legal and regulatory duties** such as:
  - Ensuring the study is conducted according to good clinical practice
  - Making required disclosures to IRB(s), or government or regulatory authorities
  - Seeking approval from government or regulatory authorities to market the study drug
    - It is possible that these government or regulatory authorities may disclose your Coded Information to other researchers for the conduct of future scientific research
  - Sharing study data with other researchers not affiliated with the study staff or Pfizer. This includes through publication on the internet or other ways. However, information that could directly identify you will not be made available to other researchers
- **Publishing summaries of the study results:**
  - In medical journals
  - On the internet
  - At educational meetings of other researchers

  You will not be directly identified in any publication or report of the study. But some journal representatives may need access to your Coded Information to verify the study results and ensure the research meets the journal's quality standards. Also, journals may require that genetic and other information from the study that does not directly identify you be made available to other researchers for further research projects.
- **Improving the quality, design, and safety** of this study and other research studies

How are my biological samples handled?

If biological samples are taken during the study, those samples will be handled in the same way as your Coded Information. All samples will be treated as required by law.

Can my coded information and biological samples be used for other research?

Your Coded Information and biological samples may be used in other research projects to advance scientific research and public health. At this time, we do not know the specific details of these other research projects.

Study-Related Injuries

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

- The name or number of the study
- The CRU 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 healthcare provider if they need more information about the research study to provide the best treatment for you.

If you experience a research injury, the CRU 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.

You must call the study investigator immediately if you experience a research injury. The number is listed on the first page of this consent document. 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

This is 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). This is in keeping with CMS reporting requirements. Pfizer will not use this information for any other purpose.

A new public health declaration, called the Public Readiness and Emergency Preparedness Declaration (PREP), was issued by the Department of Health and Human Services on March 10, 2020. This declaration limits the legal rights of a subject participating in a COVID-19 clinical study that uses a drug, device or vaccine designed to treat, diagnose, cure, or prevent COVID-19. This includes the study drug PF-07817883 used in this study. Participants using PF-07817883 in this study will have limits on their right to sue the manufacturers, the study sponsor, healthcare providers and others for significant injuries and adverse reactions.

Legal Rights

You will not lose any of your legal rights by signing and dating this consent document.

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;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study investigator’s or study site’s decision to withdraw you from participation;
- Results of tests and/or procedure;

Please contact the study investigator 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:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00066581.

Link to Additional Information

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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.

Payment for Taking Part in the Study

The amount of payment is based on a number of things including the length of the study. Travel pay for this study has been included in the payment.

You may be eligible for a travel and hotel bonus payment:

- $0.20/mile per one-way trip to or from the CRU based on your home address
- For participants traveling long distances, a 1-night hotel stipend ($150.00) for the night prior to your visit(s), if needed

Additional travel services may be arranged on your behalf at no cost to you.

All payments will be in U.S. 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.

U.S. Citizens: Payments may be considered taxable income. If you receive $600.00 or more in taxable payments within a calendar year, your earnings will be reported to the Internal Revenue Service (IRS) and you may receive a tax form (1099). Personal information about you, such as your name, address, and Social Security Number (SSN) or Tax Identification Number (TIN), may be provided to the IRS and vendors working on behalf of Pfizer for tax purposes. If you do not provide your SSN or TIN, you may have taxes deducted from your payment at a rate of 24% and receive a tax form (1099). If you prefer to not receive payment for this study, you may alert your study site. In some countries, compensation may not be allowed due to immigration status.

Non-U.S. Citizens: Payments may be considered taxable income. Your earnings will be reported to the Internal Revenue Service (IRS) and you may receive a tax form (1042-S). Personal information about you, such as your name, address, and Social Security Number (SSN) or Tax Identification Number (TIN), may be provided to the IRS and vendors working on behalf of Pfizer for tax purposes. If you do not provide your SSN or TIN, you may have taxes deducted from your payment at a rate of 30% and receive a tax form (1042-S). If you prefer to not receive payment for this study, you may alert your study site. In some countries, compensation may not be allowed due to immigration status.

If at any time you test positive for drugs of abuse, you will not be paid for your visit. Further, if you test positive for drugs of abuse:

- You will not be allowed to be in this study
- You may not be allowed to be in any future studies

Screening Payments

The screening payment is listed below. You will receive this payment within 2 weeks of screening. If you leave the screening early, you will not be paid.

Screening Visit at CRU	$175.00

Additional payments are made if we ask you to return to the CRU to repeat any screening tests ($100.00 per visit).

Study Payments

The payment for completing the entire study is listed below. Please be aware that:

- 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 may be reduced. You will be paid a prorated 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
- You will not be given the study completion bonus if you drop out of the study early
- Partial payments are planned during the study. Details will be provided at screening
- A final payment will be provided to you within 2 weeks of finishing the study
- Pfizer may use information resulting from the study or samples collected in the study to develop products or processes. Pfizer may make a profit from these. 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 study

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

STUDY PARTICIPANTS		
Type of Activity	**Payment per Activity**	**Total Number**
Overnight Stay*	$258.00	20 nights
Duration of Follow-Up Period (Discharge to Follow-Up Phone Call)	$15	24 days
Follow-Up Phone Call	$100.00	1
Completion Bonus	$1,390.00	
Total Payment	$7,010.00	

BACK-UP PARTICIPANTS	
Type of Activity	**Payment per Activity**
Overnight Stay*	$300.00
Daytime Stay	$190.00

*Overnight stay rates include an increase for COVID restriction inconveniences

Additional payments are made if we ask you to return to the CRU or to outside medical providers for additional tests ($250.00 per visit). During times that you need to stay in the CRU, you will not be paid more for repeat or added tests.

Costs for Study Participants

The study drug, study-related procedures, and study visits will be provided at no cost to you.

Your Decision to be in the Study

Taking part in this study is voluntary. You cannot be forced 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, 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 New Haven 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 CRU for a final visit. You may have some end of study tests at this visit. This is to make sure it is safe for you to leave the study. 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. If you would like to have this done, please contact 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

New Findings

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

AGREEMENT TO BE IN THE STUDY PIMS # _____

This consent document 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 document, 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 document is written in a language I understand	
B.	I understand the information in this consent document	
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 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 cannot 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 AND DATE THIS CONSENT DOCUMENT

Text Messages:
Please check the box next to your choice.

☐ Yes, I agree that the study staff may send me text messages as described in the Confidentiality section

☐ No, I do NOT agree that the study staff may send me text messages as described in the Confidentiality section

- 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 Participant (Name as appears on U.S./State Government-Issued ID)

Signature of Adult Study Participant Date

Printed Name or Initials of Person Explaining Informed Consent

Signature of Person Explaining Informed Consent Date