INFORMED CONSENT FORM AND

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

CTgov Identifier:	**NCT05582187**
Sponsor / Study Title:	**Basilea Pharmaceutica International Ltd, Allschwil / "A PHASE 1, OPEN-LABEL, SINGLE-DOSE, PARALLEL COHORT STUDY TO ASSESS THE PHARMACOKINETICS AND SAFETY OF FOSMANOGEPIX (PF-07842805) IN ADULT PARTICIPANTS WITH VARYING DEGREES OF HEPATIC IMPAIRMENT"**
Protocol Number:	**C4791019**
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Each and every person plays a powerful role in clinical research

Every approved medicine we have today was tried and tested in a clinical study. With your participation, and the help of countless others, we are working toward developing therapies to improve the lives of people worldwide.

Brief Summary of Study

After signing this informed consent form and meeting study eligibility criteria, you will be enrolled and confined to the clinical research unit (CRU) from Day-1 to Day 5 or Day 11 (as appropriate) and will receive 1 oral (by mouth) dose of [redacted] mg or [redacted] mg of a study drug called fosmanogepix. On Day 1 serial pharmacokinetic (PK, which measures the amount of study drug in the body) blood samples (pre-dose and 1, 2, 3, 4, 5, 6, 12 hours post dose; to check the blood levels of fosmanogepix and manogepix, which is an active molecule that is part of fosmanogepix, in your body), plasma protein binding (PPB, the degree to which manogepix will attach to proteins within the blood) samples (pre-dose and 3 hours post dose) for manogepix; a genetic (may include your genes) sample (pre-dose), and safety assessments, will also occur.

Following the last assessment for Day 5 or 11 (as appropriate), you will be discharged from the CRU. If discharged on Day 5, you will be asked to return to CRU for safety and pharmacokinetic (PK) blood samples on Days 8 and 11. On Day 11, a brief physical examination (PE), safety laboratory assessments, electrocardiogram (ECG, a measurement of your heart's electrical activity) and vital signs will be obtained. A telephone call to check on your status will occur

approximately 28-35 days after the dose administration of fosmanogepix (Day 1). Study duration from the screening visit to the follow-up visit is at a minimum 4 weeks and up to a maximum of 9 weeks.

The most common risks are headache, dizziness, nausea, vomiting, and fatigue (tiredness). Potential risks based on animal studies include damage to the testes, liver, and nervous system.

Introduction and Purpose of Study

You are being asked to take part in a study that is sponsored by Basilea (the "Sponsor"). The Sponsor is providing funding to the study doctor to conduct the study.

This study is different from your regular medical care. The purpose of regular medical care is to improve or otherwise manage your health, but the purpose of research is to gather information to advance science and medicine and does not replace your medical care.

You are being asked to take part in this study because you have impaired hepatic (liver) function or normal hepatic function. This study will explore the PK and safety of fosmanogepix after dosing in participants with mild, moderate, and severe hepatic impairment, and in participants with normal hepatic function. Findings from this study will be used to develop dosing recommendations so that the dose and/or dosing interval may be adjusted appropriately in the presence of hepatic impaired participants. The study drug, fosmanogepix, is an investigational drug because it is not approved for use by the United States by the Food and Drug Administration (FDA).

This research study is different from, and does not replace, your regular medical care. As such, if you participate in this study you may have additional visits, procedures, extra laboratory tests, and/or follow a modified treatment plan. You will be asked to take part in the study for up to 9 weeks. You will be assigned to receive a single dose of fosmanogepix [redacted] mg tablet or [redacted] mg tablets (2 tablets of [redacted] mg) orally on Day 1 of the study. Both you and your study doctor will know you are receiving fosmanogepix.

You may be asked to provide biological samples (such as blood) and undergo procedures that might be different from a regular medical examination. This study will involve screening tests to determine your eligibility (demographics, medical and medication history, safety assessments [laboratory tests including SARS-CoV-2 RT PCR, ECG, PE, vital signs, body weight and height]). The study doctor will determine whether you are eligible for the study.

If you join, you will receive the study drug, fosmanogepix. This study will require you to visit the CRU for a screening visit, then a confinement visit in the CRU for Day-1 through Day 5 or 11. Study Treatment will be on Day 1 only and you will be discharged from the CRU after your last blood sample on Day 5 or Day 11 (as appropriate). You will be allowed to reside at home, however, you must return to the CRU for additional PK and safety assessments during the remainder of the assessment period and abide by the Lifestyle Guidelines which are required for the PK assessments (i.e., contraceptive methods; alcohol, tobacco, caffeine restrictions; dietary restrictions) and to provide information about your health. During this assessment week following fosmanogepix treatment, you will have blood samples taken for safety laboratory tests and also to assess fosmanogepix concentration taken at multiple timepoints. COVID-19 risk assessment and SARS-CoV-2 RT PCR will be performed at any time you may be symptomatic

for COVID-19. The study doctor may be required by law to report the result of these tests to the local health authority.

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

Taking part in this study is voluntary (your choice). There is no penalty or change to your regular medical care if you decide not to participate. You can choose to take part in the study now, and then change your mind later at any time without losing any benefits or medical care to which you are entitled. We encourage you to have conversations with your family, caregivers, doctors, and study team about taking part in this study and whether it is right for you. The study team will work with you to answer any questions that you may have about the study.

Your personal information will be protected during this study in the manner described in the accompanying Privacy Supplement.

This study has been reviewed by the relevant authorities in your location.

If you decide to take part, the first thing you will be asked to do is to sign this informed consent form. You will get a signed copy to take home. Please keep this informed consent form for your reference.

A. About the Study

1. Number of Study Participants

There will be at least 27 participants taking part in this study. The study is taking place at two research sites in the USA.

2. Length of Study for Participants

Participants will be taking part in this study for a minimum of 4 weeks and up to a maximum of 9 weeks. If you are enrolled, you will need to visit the research site a maximum of 4 times (including 1 screening visit, 1 confinement period, Day -1 to Day 5 or 11 [as appropriate]), and have 1 follow-up phone contact to end the study approximately 28-35 days after your fosmanogepix dose (Day 1).

3. Process for Selecting Study Participants

After you sign this informed consent form, the study will start with a screening visit. This is to learn about your medical history and to check if you meet the study requirements. If you do not meet the study requirements, you will not be able to take part. The study doctor will explain why and discuss other options with you, if available. If you meet the study requirements, you will be required to follow the study requirements.

Participants enrolled in this study will be male or female 18-75 years of age, body mass index (value derived from the mass and height of a person) between 17.5-40.0 kg/m^2 (42 kg/m^2 for participants with severe hepatic impairment), and a total body weight of greater than 50 kg (greater than 110 lbs). Participants with hepatic impairment, in stable general health, may be on stable concomitant medications. They have a Child-Pugh classification for mild, moderate or severe liver dysfunction, and must also follow the Lifestyle Guidelines associated with PK testing (detailed later in this informed consent form).

Participants with normal hepatic function will be age- and weight- matched with the participants with hepatic impairment diseases.

The following screening procedures, in no particular sequence (except informed consent must occur first and CRU confinement last), will occur to determine your eligibility for the study, during Day -28 to Day-1, additional details are located in Appendix A "Study Tests, Procedures And Assessments And Associated Risk Details" of this form:

Informed Consent Form	Safety Laboratory Tests
Demographics	Human immunodeficiency virus (HIV) and hepatitis blood tests- The study doctor may be required by law to report the result of these tests to the local health authority
Medical/Medication History/Concomitant Medication/Non-Drug Treatments	Illicit drug and alcohol tests
Electrocardiogram and Physical Examination	Vital signs (height, weight, blood pressure, pulse rate, body temperature)
Pregnancy or Follicle Stimulating Hormone (FSH) test (females only)	Contraceptive check
Eligibility criterion check, including Child-Pugh assessment (participants with hepatic impairment only)	COVID-19 status/temperature/SARS-CoV-2 RT-PCR test (if applicable)
Adverse event (side effect)/Serious adverse event check	Confinement to CRU starting on Day-1

Study Drug(s)

All participants will be assigned the same study drug after meeting study eligibility and Lifestyle Guidelines criteria (contraception; meals and dietary restrictions; caffeine, alcohol, tobacco and activity restrictions, defined in a later section of this form).

The study drug, fosmanogepix [redacted] mg tablet or [redacted] mg tablets (2 tablets of [redacted] mg) orally will be provided to you in one single dose by the CRU staff while you are at the CRU.

4. Post Study Access to the Study Drug

Because researchers are still studying this drug, you can only have fosmanogepix during your participation in the study, and not after you have finished taking part.

5. Study Tests, Procedures and Assessments

In this research study, you will have certain tests, procedures, and assessments. The study doctor may ask you to come in for additional tests, procedures and assessments, if necessary, to protect your health.

A more detailed description of the tests, procedures and assessments that will be required in this study can be found in *Appendix A Study Tests, Procedures and Assessments and Associated Risks Details*.

Required procedures/assessments for this study, including the number of times required (in parentheses):
Informed consent (1)
CRU confinement/discharge (1)
Demography (1)
Eligibility criteria check (2)
Medical/Medication history (2)
Complete physical examination (1), brief physical examination (1)
Vital signs (blood pressure, pulse rate, temperature) (3)
Safety laboratory tests (3)
Alcohol and tobacco use, alcohol testing (2), urine drug testing (2)
HIV and hepatitis blood tests (1)
Serum or urine pregnancy test (3) or Follicle Stimulating Hormone test (1) (females /post menopausal female only)
Contraception check (4)
Electrocardiogram (3)
Body weight and height (1)
COVID-19 testing/risk assessment (1, and as needed)
Child-Pugh classification (1) (participants with hepatic impairment only)
Study drug administration (1)
Blood samples for pharmacokinetics (13)
Blood sample for plasma protein binding (2)
Blood sample for genetics (1)
Concomitant medication review (9)
Adverse event/serious adverse event check (9)
Follow-up phone call to check on status (1)

Biological Samples

You must provide biological samples in order to take part in this study. These samples taken from you may be sent to or stored in a foreign country. Additional samples may be collected depending on the results of your laboratory tests or if a replacement sample is needed. Companies hired by the Sponsor may be involved in the collection, transportation, analysis and/or storage of these samples.

The total volume of blood samples during the study will be 120 mL (about ½ cup) for male participants and 145 mL (about 2/3 cup) for female participants. By comparison, a blood donation generally represents approximately 480 mL (2 cups) of blood, which is taken in one day.

Stopping Study Drug and Impact on Study Tests, Procedures and Assessments

If for any reason you are asked to stop taking the study drug or the study participation or you want to stop taking the study drug or your study participation, you will have the early discontinuation procedures/assessments performed and will continue with a follow-up telephone call 28-35 days after your last fosmanogepix dose (Day 1).

The discontinuation procedures include all procedures listed under "End of Study Procedures" (see below).

End of Study Procedures

Procedures which will occur on Day 11 (end of intervention period): final PK blood sample, physical examination, vital signs, ECG, safety blood tests, pregnancy test and contraceptive check, concomitant medication and adverse event checks.

Follow-up Procedures

The study doctor will contact you by telephone 28-35 days after your fosmanogepix dose (Day 1). The study doctor may ask you to come back for a visit to check on your well-being.

6. 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.

Side effects might be mild or serious. The study doctor may determine that you need additional procedures or medicines to help manage the side effects.

It is important that you report all symptoms and side effects to the study team as soon as they happen, even if you feel the study drug or procedure was not the cause.

Fosmanogepix is a new agent being developed for the treatment of invasive fungal infections.

Side effects of fosmanogepix

Up until 31 January 2025, fosmanogepix had been studied in more than ten clinical studies with over 300 participants, who received at least one dose of fosmanogepix administered either into a vein or by mouth. In addition, more than 200 participants received fosmanogepix upon request by their treating physician to treat infections in cases where no other appropriate medication was available.

Side effects of fosmanogepix reported in more than 10% of study participants included:

- Feeling sick (nausea)
- Headache
- Being sick (vomiting)

Side effects of fosmanogepix reported in more than or equal to 2% up to 10% of study participants included:

- Dizziness
- Tiredness (fatigue)
- Diarrhea
- Feeling drowsy
- Injection site complaints (pain, irritation)

Side effects reported in less than 2% of study participants included:

- Stomach discomfort
- Decreased appetite
- Feeling of body temperature change
- Chest discomfort
- Chest pain
- Change in the way things taste
- Increased values of liver test results
- Loss of contact with reality (delirium)
- Head discomfort
- Hot flush

One participant given study treatment with fosmanogepix experienced serious nervous system side effects related to fosmanogepix, with symptoms of mental changes, changes in motor tone / movement, and seizures, from which the participant recovered.

In the studies, in which a total of 114 participants received a single dose or multiple low doses of fosmanogepix, side effects were generally less frequent, and most were mild, transient, and did not require treatment.

Some study participants had increases in levels of enzymes of the liver without feeling anything.

The safety of fosmanogepix has also been studied in animals. When samples of tissue were looked at under the microscope, adverse changes were seen in the tissue of the liver. There were also signs of temporary adverse effects on the nervous system including shaking (tremors). The levels of fosmanogepix in the animals' blood associated with these changes were in some cases at the levels or lower than those anticipated in humans. Levels of manogepix (the active moiety of fosmanogepix) were not always tolerated in animals. In some cases, this resulted in death that was preceded by adverse effects on the nervous system and gastrointestinal system.

Based on animal studies, there is a possibility of a potential impaired fertility in men and women. In studies in minipigs (but not in rats or monkeys), structural changes were seen in reproductive organs (testes and the epididymides) when given fosmanogepix which were considered to be at least partially reversible after 6 months. At 6 months, these changes were comparable to changes seen in animals which did not receive fosmanogepix. It is unclear if these findings are relevant to humans. The epididymides is a narrow, tightly-coiled tube that is attached to each of the testicles. Sperm cells move from the testicles into the epididymis, where they finish maturing and are stored.

In studies in pregnant rats and rabbits, some baby rats and rabbits were born with developmental abnormalities. This suggests that fosmanogepix may carry a risk of causing birth defects if taken during pregnancy.

Fosmanogepix is an experimental drug with limited safety information beyond 6 weeks of administration. Fosmanogepix use may involve the risk of unforeseeable adverse reactions of unknown severity, potentially including the risk of a fatal adverse reaction.

The study assessments are designed to carefully monitor your health throughout the study; this will include blood tests to monitor your liver function and physical examinations to check your nervous system function for any changes.

Risks from Study Procedures

A description of the possible risks and discomforts associated with the tests, procedures and assessments required in this study can be found in Appendix A *Study Tests, Procedures and Assessments and Associated Risk Details*.

Other Risks

Fosmanogepix is an experimental drug with limited safety information beyond six weeks of administration. Fosmanogepix use may involve the risk of unforeseeable adverse reactions of unknown severity, potentially including the risk of a fatal adverse reaction.

All drugs have a potential risk of causing an allergic reaction, which (if not treated quickly) could become life-threatening. You should get medical help right away or call your local emergency number and contact the study doctor 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, or blisters.

7. Birth Control and Pregnancy-Related Risks

Taking the study drug might also involve unknown risks to a pregnant woman, an embryo, unborn baby, or nursing infant. Therefore, if you (for women) are pregnant, planning to become pregnant, or are breastfeeding a child, you cannot take part in this study.

Before entering the study, a pregnancy test will be done for all women who are able to become pregnant. This test might not detect an early pregnancy. Pregnancy tests (blood or urine) will be repeated during the study.

Fosmanogepix may cause harm to the fetus when administered to a pregnant woman. This has been seen in animal studies. Because it is not known whether fosmanogepix passes into human breast milk, nursing mothers cannot participate in this study.

Use of Birth Control

Males: no contraception methods are required for male participants in this study. Reversible testicular changes have been demonstrated in animals. Male participants should be aware of the potential risk of testicular toxicity and impaired fertility.

Women, post-menopausal: is defined as a female with no menses for 12 months without an alternative medical cause; no contraception methods are required for women meeting this definition.

There is evidence from animal studies that suggests there may be a risk to female fertility and a serious risk to the unborn baby if you become pregnant. At timepoints indicated in Appendix A "Study Tests, Procedures and Assessments and Associated Risk Details" of this informed consent form, the study doctor or team will discuss with you regarding the need to use effective birth control consistently and correctly. You will need to affirm your consistent and correct use of at least 1 of the selected methods of birth control. You are asked to immediately notify the site if the selected birth control method is discontinued. Contraceptive use by men or women should be consistent with local availability/regulations regarding the use of contraceptive methods for those participating in clinical trials.

Women of child-bearing potential (WOCBP): A female participant is eligible to participate if she (a) is not pregnant or breastfeeding; and (b) agrees to not donate eggs (ova, oocytes) for the purpose of reproduction for at least 28 days after the last dose of study intervention (Day 1); and (c) at least 1 of the following conditions applies:

- Is a WOCBP and agrees to use a highly effective contraceptive method (failure rate of less than 1% per year) with low user dependency from screening through the intervention period and for at least 28 days following the last dose of study intervention (Day 1), which corresponds to the time needed to eliminate any reproductive safety risk of the study intervention.

OR

- Is a WOCBP and agrees to use a highly effective (failure rate of less than 1% per year) user-dependent method of contraception from screening through the intervention period and for at least 28 days following the last dose of study intervention (Day 1), which corresponds to the time needed to eliminate any reproductive safety risk of the study intervention. In addition to her use of the highly effective method above, she agrees to concurrently use an effective barrier method.

The following contraceptive methods are appropriate for this study:

Highly Effective Methods That Have Low User Dependency

- Implantable progestogen only hormone contraception associated with inhibition of ovulation.
- Intrauterine device.
- Intrauterine hormone releasing system.
- Bilateral tubal occlusion.
- Vasectomized partner:
    - Vasectomized partner is a highly effective contraceptive method provided that the partner is the sole sexual partner of the WOCBP and the absence of sperm has been confirmed. If not, an additional highly effective method of contraception should be used. The spermatogenesis cycle is approximately 90 days.

Highly Effective Methods That Are User Dependent

- Combined (estrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation:
    - Oral + barrier□
    - Intravaginal + barrier□
    - Transdermal + barrier□
- Progestogen only hormone contraception associated with inhibition of ovulation:
    - Oral + barrier*
    - Injectable + barrier□
- Sexual Abstinence is considered a highly effective method only if defined as refraining from heterosexual intercourse during the entire period of risk associated with the study intervention.

* Acceptable barrier methods to be used concomitantly with options hormonal contraception for the study include any of the following:

- 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 methods).

Pregnancy-Related Risks

You cannot participate in the study if:

- You are pregnant, planning to become pregnant, or breastfeeding a baby.

The study drug may have unknown risks that could harm you, a fetus, or a breastfeeding baby.

Pregnancy Follow-Up

If you become pregnant during the study or within 28 days after you have stopped taking the study drug, tell the study doctor immediately. Also tell the health care provider(s) taking care of you during the pregnancy that you took part in this study.

The study doctor will ask if you or your health care provider(s) are willing to provide updates on the progress of the pregnancy and its outcome. If you agree, this information will be provided to the sponsor for safety follow-up.

8. Possible Benefits of Participation

A single dose of fosmanogepix administered in this study is not expected to provide any clinical benefit to study participants. Your participation may help future patients by increasing our understanding of hepatically impaired participants with fosmanogepix treatment. It is possible your condition or health may improve, worsen, or stay the same.

9. Other Options instead of this Study

Other options may be available to you if you choose not to participate in this study. Talk to the study doctor or your regular doctor about these other options.

The study doctor will discuss with you the major risks and benefits of the standard of care and alternative treatment options.

B. Participant Responsibilities & Rights

1. SPECIAL INSTRUCTIONS FOR STUDY PARTICIPANTS

You must:

- Be willing and able to follow all scheduled visits, instructions about the study drug, lab tests, and other study procedures.
- Tell the study team if you have already taken part in this study (at this site or any other location), have taken part in any other study during the past year, or are now taking part in any other study or want to take part in another study.

- Follow instructions you are given by the study team and discuss all prescription and non-prescription medications, supplements, or vaccines before you take them.
- Notify the study team if you move and provide your new contact information.
- Abide by the Lifestyle Guidelines as required for PK testing:
    - Contraception: use of appropriate and consistent contraception (defined earlier in this informed consent form).
    - Meals and dietary restrictions
        - Participants must abstain from all food and drink (except water) at least 4 hours prior to any safety laboratory evaluations and 10 hours prior to the collection of the predose PK sample.
        - Water is permitted until 1 hour prior to study intervention administration. Water may be consumed without restriction beginning 1 hour after dosing. Non-caffeinated drinks (except grapefruit or grapefruit-related citrus fruit juices, see below) may be consumed with meals and the evening snack.
        - Lunch will be provided approximately 4 hours after dosing.
        - Dinner will be provided approximately 9 to 10 hours after dosing.
        - An evening snack may be permitted.
        - Participants will refrain from consuming red wine, grapefruit, or grapefruit-related citrus fruits (e.g., Seville oranges, pomelos, fruit juices) from 7 days prior to taking the study drug until collection of the final PK blood sample.
        - While participants are confined, their total daily nutritional composition should be approximately 55% carbohydrate, 30% fat, and 15% protein. The daily caloric intake per participant should not exceed approximately 3200 kcal (provided by the CRU).
    - Caffeine, alcohol, and tobacco
        - Participants can consume caffeinated drinks during study participation, however, will abstain from caffeine containing products for at least 2 hours prior to any scheduled electrocardiogram or blood pressure determination.
        - Participants will abstain from alcohol for 24 hours or more (or as specified above for red wine) prior to admission to the CRU (*plus* have a negative breath alcohol test on Day -1) and continue abstaining from alcohol until collection of the final PK sample.
        - Smoking may be allowed according to CRU practices. Smoking will not be permitted during frequent sampling procedures, and will not be permitted within 2 hours prior to any vital sign or electrocardiogram

assessments. Smoking will also not be permitted 2 hours before and 2 hours following study drug dose.

- Activity level
  - Participants will abstain from strenuous exercise (e.g., heavy lifting, weight training, calisthenics, aerobics) for at least 48 hours prior to each blood collection for clinical laboratory tests. Walking at a normal pace will be permitted.
  - In order to standardize the conditions on PK sampling days, participants will be required to refrain from lying down (except when required for blood pressure, pulse rate, and electrocardiogram measurements), eating, and drinking beverages other than water during the first 4 hours after dosing.
- Confinement Period: participants will be required to stay at the CRU from Day -1 through Day 5 or 11 (as appropriate).

You should also tell your regular doctor that you are taking part in this study.

2. PROCESS FOR PARTICIPANTS WHO WISH TO END STUDY PARTICIPATION

You can stop being in the study at any time. Your decision will not affect your regular medical care or any benefits to which you are entitled. Tell the study doctor if you decide to stop so that you can end participation in the safest way. The study doctor will explain what other steps may occur.

While you are participating, the study doctor will tell you in a timely manner if new information is learned that could change your mind about being in this study.

The study doctor may also decide to take you off the study drug and/or remove you from the study (even if you do not agree) in the following situations:

- You are unable or unwilling to follow the instructions of the study;
- The study doctor decides that the study is not in your best interest or that you are no longer eligible to be in the study; or
- The study is stopped by the Sponsor, an institutional review board (IRB) or independent ethics committee (IEC) (a group of people who review the study to protect your rights), or by a government or regulatory authority, such as the FDA.

Information about your health will continue to be collected and used as described in the Follow-up Procedures section above and in the Privacy section.

You may request that any samples that have been collected from you as part of the study be destroyed, and in some countries, local laws or regulations may require that your samples be destroyed regardless of whether you specifically make such a request. However, we cannot guarantee the destruction of samples because, for example, the samples may no longer be traceable to you or the samples may have been used up.

3. STUDY-RELATED INJURIES

You will also be given a card with important emergency contact information, including a 24-hour phone number. Show this card to any health care provider if you seek emergency care during this study. This card includes information about the study that will help the health care provider to treat you.

If you experience a research injury, the study doctor will provide or arrange for medical treatment. Basilea will cover the costs of this treatment. A research injury is any physical injury or illness caused by your participation in the study. If you are injured by a medical treatment or procedure that you would have received even if you were not in the study, that is not a research injury. There are no plans to offer you payment for such things as lost wages, expenses other than medical care, or pain and suffering. To help avoid injury, it is very important to follow all study directions. You are not giving up any of your legal rights by signing this informed consent form.

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

4. COSTS FOR STUDY PARTICIPANTS

You will not have to pay for the study drug or study-related procedures and visits. Talk to the study doctor if you have any questions about costs resulting from participating.

5. PAYMENT FOR TAKING PART IN THE STUDY

«Compensation»

You will be paid *[per visit amount]* for each planned study visit you complete. If you leave the study early for any reason, you will be paid *[per visit amount]* for each study visit you have already completed. You will be paid by *[enter method and schedule of payment]*.

You will be reimbursed by the study site for reasonable expenses (such as parking, meals, travel) you may have while taking part in this study. You will be paid by *[enter, as applicable, method of payment, amounts, and payment schedule; note whether receipts are required]. Consider adding participant payment schedule in a table or similar graphic.]*

Payments may be considered taxable income. If you receive [redacted] 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 for tax purposes. If you do not provide your SSN or TIN, you may have taxes deducted from your payment and receive a tax form (1099). If you prefer to not receive payment for this study, you may alert your study site.

The Sponsor may use information and biological samples resulting from 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 study. The Sponsor will own all products or processes that are developed using information and/or biological samples from the study.

6. MAINTAINING CONFIDENTIALITY AND USE OF MEDICAL AND RESEARCH RECORDS

Medical and research records collected during this study will be stored by the study team at your study site and may also be stored on a third-party cloud-based platform paid for by the Sponsor. These medical and research records will be reviewed to verify that clinical trial procedures and/or data are correct.

Your medical and research records may be accessed by:

- Your study doctor and other study team members;
- The Sponsor and its representatives (including its affiliated companies);
- People, or organizations providing services for, or collaborating with, the Sponsor;
- Other researchers, including researchers involved in the study at sites other than the one at which you are participating in the study;
- Any organization that obtains all or part of the Sponsor's business or rights to the product under study;
- Government or regulatory authorities, such as the FDA, including those located in other countries; and
- [redacted] Institutional Review Board (IRB) overseeing this study.

In order to keep records that identify you confidential, the study site will replace your name with a unique code. The records and information labelled with the code are called "**Coded Information**." The study site will keep the link between the code and your name confidential. Your information will be transferred to the Sponsor using the unique code assigned to you. The Sponsor's employees and those with whom your Coded Information is shared are required to protect your Coded Information and will not attempt to re-identify you. While every effort will be made to protect the confidentiality of your information, absolute confidentiality cannot be guaranteed.

Your personal information will be collected, used, and shared (together called "processing") in compliance with applicable privacy laws.

The people and/or organizations contracted by the Sponsor to provide these services must keep your personal information private, and they will not share with the Sponsor any information that can directly identify you.

You will also be provided a separate Privacy Supplement (which is considered part of this informed consent form) that further describes how your information, biological samples, and/or images will be processed and your privacy rights.

7. WHOM TO CONTACT ABOUT THIS STUDY

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

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

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

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

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

- [redacted]

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.

If you need assistance to understand the content in a different language, please ask a member of the study team.

The study results, when available, may also be found on http://www.ClinicalTrials.gov. However, your individual overall study results will not be given to you, your doctor (if different from the study doctor), your family, your employer or any insurance company. If any exploratory research is done, it may not be possible to link any results from that exploratory research to specific individuals, including you. The Sponsor does not plan to return information

from any exploratory research to you, the study doctor, or your doctor (if different from the study doctor).

The Sponsor will provide the study doctor with information about the study results when all participants have completed the study.

8. BARDA CERTIFICATE OF CONFIDENTIALITY

This research is in part funded by the Biomedical Advanced Research and Development Authority (BARDA), Administration for Strategic Preparedness and Response, a U.S. Federal Government entity under the Department of Health and Human Services (DHHS), and covered by a Certificate of Confidentiality (CoC) from BARDA.

This means that the staff of Basilea, and their subcontractors cannot share or give to any other person not connected with this research your name, information about you, documents, or samples that may identify you, including in any legal action or suit, unless you say it is okay.

A CoC protects your private information from all legal proceedings. Your information cannot be used as evidence even if there is a court subpoena. All copies of your information are immune from the legal process, and cannot, be admitted as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding unless you say it is okay.

The information about you **can** be shared for other research if it is allowed by Federal regulations. We will let you know beforehand if this is something we will do.

The Certificate **does not** stop the reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate **cannot be used to** stop a United States federal or state government agency from checking records or evaluating programs. The Certificate **does not** stop disclosures required by the federal Food and Drug Administration (FDA).

A CoC does not keep you from voluntarily releasing information about yourself or your involvement in this research. It also does not prevent you from having access to your own information. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide specific consent to allow the researchers to release it.

9. FUTURE RESEARCH STUDIES

Identifiers might be removed from your identifiable private information or identifiable biospecimens collected during this study and **could then be used for future research studies or distributed to another study doctor for future research studies** without additional informed consent.

10. GENOME SEQUENCING

Researchers can look closely at large amounts of your genetic information by sequencing, or "reading", every letter in your DNA (your genome). Reading a person's entire genetic code is called whole genome sequencing. The research **might include** whole genome sequencing (for example, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

C. Signatures

I have had enough time to read this informed consent form (or, if I cannot read, an Impartial Witness ‡ has read it to me) and have had the opportunity to ask questions. All of my questions have been answered to my satisfaction. I have been told that my participation is voluntary and I can refuse to participate or withdraw at any time. I agree to take part in the study.

I also acknowledge that I have received a copy of the Privacy Supplement.

Printed Name of Participant	
Signature of Participant	Date of Signature (dd-Mmm-yyyy)§

§ Participant must personally date their signature.

Person Obtaining Informed Consent:

Printed Name of the Person Conducting the Informed Consent Discussion	
Signature of the Person Conducting the Informed Consent Discussion†	Date of Informed Consent Discussion (dd-Mmm-yyyy)†

† The study doctor, or an appropriately qualified and trained person designated by the study doctor to conduct the informed consent process, must sign and personally date the informed consent form.

Informed Consent for Participant Who Cannot Read or Cannot Write, If Applicable:

The study participant has indicated that he/she is unable to read or is unable to write. I read the informed consent form to the study participant and one or more members of the study team discussed it with the study participant and gave the study participant an opportunity to ask questions. The information in the informed consent form was accurately explained to, and

apparently understood by, the study participant, who provided informed consent to participate in the study.

Printed Name of Impartial Witness‡

Signature of Impartial Witness | Date of Signature (dd-Mmm-yyyy)§

§ Impartial witness must personally date their signature.

‡ Impartial Witness: A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the entirety of the informed consent process if the participant cannot read or cannot write, and who reads the informed consent form and any other written information supplied to the participant. Refer to the GUIDANCE FOR INDUSTRY, E6 Good Clinical Practice: Consolidated Guidance; EU Clinical Trial Regulation 536/2014 Art. 29(1).

Thank you for your participation

Your participation in this study matters. Your study team is here to support you throughout your journey with us, and we at Basilea want to sincerely thank you for your time and commitment to this research.

PRIVACY SUPPLEMENT

A U.S. privacy law called HIPAA (the Health Insurance Portability and Accountability Act of 1996) protects the privacy of your personal information held by most health care providers. The study doctor/study site must get your permission (called an "authorization") to use and share with others for research purposes any personal information that could identify you.

This Privacy Supplement describes how the study site and the Sponsor will collect, use, and share your personal information.

This Privacy Supplement also describes your privacy rights.

You are not required to authorize the use and disclosure of your personal information as described below. If you do not agree to do so, you cannot participate in this study, but there will be no penalty or change to your regular medical care or payment for that care.

The study doctor/study site is required by HIPAA to protect your personal information. By signing this form, you authorize the study doctor/study site to use and share your personal information as described below. After your personal information is shared with others, such as the Sponsor, it may no longer be protected by HIPAA and may be re-disclosed to other third parties as described in this Privacy Supplement and in the main informed consent form.

A. What information may be collected about you during this study?

In order to conduct the study and comply with legal and regulatory requirements, your study team will collect information about you. Information about you may include information that directly identifies you, demographics, and sensitive information such as your medical history and data from this study (including diagnoses, treatment, genetic information, sexuality, and race). If required by this study, the study team may also collect biological samples from you and take images or make audio/video recordings of you.

Information may be collected from electronic devices if you use a mobile application or other digital tool during the study. You should review the main informed consent form as well as the terms and conditions and privacy policy of any digital tool or mobile application used in the study to understand further how information collected through those digital tools and applications may be used.

If you provide an emergency contact or details of family medical history you should inform that person or those persons you have done so and that their information will be used as described in this form.

B. How will your information be used and how long will it be used?

Any information collected about you during this study will be entered into records, including health records, maintained by the study team at your study site. The site will retain your information for the period necessary to fulfill the purposes outlined in this Privacy Supplement, in the main informed consent form, and/or for the maximum period permitted by applicable law which could be at least 15 years after the end of the study.

Your information may be accessed and used by:

- The study team;
- The Sponsor (including its affiliated companies) and its representatives, for example, study monitors and auditors;
- People and/or organizations providing services to or collaborating with the Sponsor;
- Any organization that has or obtains rights to the product under study or that obtains all or part of the Sponsor's business;
- Other researchers, including researchers involved in the study at sites other than the one at which you are participating in the study;
- [redacted] IRB overseeing this study;
- Government or regulatory authorities, including the United States Food and Drug Administration and authorities located in other countries.

Typically, your name will be removed from your information before it is sent outside the study site. As described in the main informed consent form, your name will be replaced with a unique code before your information (and/or your biological samples, images and/or audio/video recordings, if collected as part of the study) leaves the study site. This information is referred to as your "Coded Information." Data generated using biological samples, images and/or audio/video recordings of you, if collected during the study, will be handled in the same way as your Coded Information, unless otherwise stated in this Privacy Supplement or the main informed consent form. Sometimes the study site may be unable to remove information that can identify you from your images, meaning that the images shared with others may be identifiable as yours.

The study site will upload your information, including information that directly identifies you, to a designated secure electronic system maintained by a third party engaged by the Sponsor. The Sponsor and/or the Sponsor's representatives will use

this secure system to review and verify study data as they would at the study site. Some of these uploaded records will be kept for the period necessary to fulfill the purposes outlined above and in the main informed consent form, as required by applicable law and/or for the maximum period permitted by applicable law on the secure electronic system. The remaining records that are uploaded will be temporary and removed/deleted from the secure electronic system after the study is over.

The individuals and groups listed above will use your information, including your Coded Information, to:

- Conduct this study;
- Comply with legal or regulatory requirements, including for all of the purposes listed in the main informed consent form that you were provided and to seek approval from government or regulatory agencies to market [study drug, device, medicine];
- Determine if you are eligible for this study;
- Verify that the study is conducted correctly and that study data are accurate;
- Answer questions from IRB(s) or government or regulatory agencies;
- Publish the results of studies;
- Contact you during and after the study (if necessary);
- Protect your vital interests or the interests of your pregnant partner (for example, a critical medical situation, such as providing information to an emergency department of a hospital where you are being treated); and
- Improve the quality, safety, and design of this study and, to the extent permitted by this Privacy Supplement, other research studies.

The Sponsor may also be required to provide information gathered from this study, including your Coded Information, to regulatory authorities for public disclosure. In such cases, the Sponsor will take steps to minimize the risk that you could be re-identified. The Sponsor will retain your Coded Information for the period necessary to fulfill the purposes outlined in this Privacy Supplement and in the main informed consent form, indefinitely or for the maximum period permitted by applicable law after the end of the study.

C. Can your Coded Information, biological samples, images, and/or audio/video recordings, if collected as part of the study, be used for other research?

The Sponsor may use your Coded Information, biological samples, images and/or audio/video recordings, if collected as part of the study, to support and advance other scientific research projects, including improving the quality, design, and safety of other research studies, research supporting public health aims, and developing medicines, vaccines, diagnostic products, and tools.

At this time, we do not know the specific details of these research projects; however, your Coded Information, biological samples, images and/or audio/video recordings, if collected as part of the study, could be used in combination with data from other sources, not related to you or this study. Reasonable safeguards will be used to protect your Coded Information, biological samples, images and/or audio/video recordings used in any future research and may include: (a) limiting access to individuals bound by duties of confidentiality; (b) taking steps to minimize the risk that you could be re-identified; and (c) obtaining approval of ethical review boards. Furthermore, if your Coded Information, biological samples, images and/or audio/video recordings, if collected as part of the study, have identifiers removed such that they can no longer readily be identified with you, they may be used for future research purposes.

D. What are your rights to your personal information?

You may have the right to access your personal information that is held by the study site.

However, by signing this authorization, you agree that your right to access certain of your information held by the study site will be suspended until after the study is over. After the study is finished, your right to access such information will be reinstated.

E. What happens to your information, biological samples, images, and/or audio/video recordings that may be collected as part of the study if you do not wish to continue with the study or if you want to withdraw your authorization for their use or disclosure under this Privacy Supplement?

As noted in the main informed consent form, you are free to stop taking part in this study at any time. If you stop taking part in the study and you do not tell the study team, your contact information may be used by the study team to contact you, your family or your personal doctor, or to search publicly available records to find out how you are doing. These uses of your information may continue until the Sponsor

determines the study is complete, which may take many years, or until you withdraw your authorization, as described below.

Your authorization for the use and sharing of your personal information under this Privacy Supplement does not expire unless you withdraw your authorization. In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign and date this authorization document.

You may withdraw your authorization for the use and disclosure of your health information by contacting the study doctor in writing. The study doctor's contact information is listed on the first page of the informed consent form.

If you withdraw your authorization:

- You will no longer be able to participate in the study; and
- No new information, biological samples, images, and/or audio/video recordings will be collected about you or from you by the study team.

Even if you withdraw your authorization:

- The study team may continue to report any adverse effects or other safety event that you experience due to your participation in the study to the Sponsor;
- Your Coded Information will continue to be used by the Sponsor to guarantee the integrity of the study, to determine the safety effects of the study drug, to satisfy legal or regulatory requirements, and/or for any other purposes permitted under applicable laws; and
- Any biological samples that have been collected from you will be handled as described in the main informed consent form.

By signing below, I authorize my personal information to be used and disclosed as described above. I understand I have a right to receive a copy of this Privacy Supplement.

_____

Printed Name of Participant

Signature of Participant	Date of Signature (dd-Mmm-yyyy)§

§ Participant must personally date their signature.

Authorization for Participant Who Cannot Read, If Applicable:

The study participant has indicated that he/she is unable to read. I read the Privacy Supplement to the study participant, and one or more members of the study team discussed it with the study participant and gave the study participant an opportunity to ask questions. The information in the Privacy Supplement was accurately explained to, and apparently understood by, the study participant, who agreed to the terms described in this Privacy Supplement.

_____

Printed Name of Impartial Witness ‡

Signature of Impartial Witness	Date of Signature (dd-Mmm-yyyy)§

☐ Not applicable (Check this box if the Signature of an impartial witness is not required. Signature of an impartial witness is required if the participant cannot read.)

§ Impartial witness must personally date their signature.

‡ Impartial Witness: A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the entirety of the informed consent process if the participant cannot read, and who reads the informed consent form and any other written information supplied to the participant. See GUIDANCE FOR INDUSTRY, E6 Good Clinical Practice: Consolidated Guidance.

APPENDIX A: STUDY TESTS, PROCEDURES AND ASSESSMENTS AND ASSOCIATED RISK DETAILS

The following is a list of the required study tests, procedures and assessments for this study, the number of times each is required and the item description (in parentheses):	**Associated risks are provided for the respective procedure/assessment:**
Informed consent (1); a document with the description of the study duration; procedures/assessments required to enroll into the study and performed during conduct and end of study; study drug information and frequency of administration; benefits and risks; reimbursement, injury and privacy information; signatures of participant, impartial witness, and study doctor (or delegate) to indicate discussion of study was conducted; questions were answered; and agreement for participation was confirmed.	No known associated risk.
CRU confinement/discharge (1); participant will be confined from Day -1 to Day 5 or 11 (as appropriate) in the CRU for prescribed meals and to ensure compliance with requirements prior to dosing and PK blood samplings.	Not residing in home environment may be inconvenient for activities of daily living during this time.
Demography (1); Demographic questions ask for personal information, such as your names, birth year, race, ethnicity, etc.	While collection of demographic information does not expose you to physical risk, collection of such information may result in a loss of your privacy if the information is lost or stolen.
Eligibility criteria check (2); certain criteria are required and excluded to meet the enrollment standard for the study.	No known associated risk.
Child-Pugh classification (1) (participants with hepatic impairment only); an assessment which calculates a score based upon 5 different parameters (laboratory values and physical assessments); the score places the participant within a defined level of either mild, moderate, or severe hepatic impairment.	No known associated risk.

The following is a list of the required study tests, procedures and assessments for this study, the number of times each is required and the item description (in parentheses):	**Associated risks are provided for the respective procedure/assessment:**
Height and weight (1); height measures how tall a participant is and weight measures the heaviness of the participant.	No known associated risk.
Medical & Medication history (2); Health and medication questions ask about your health, medical history, quality of life, medications, sexual history or practices, and thoughts of suicide, as well as any prior consumption of fosmanogepix.	Health and medication risk: These questions may be sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns after responding to these questions, you should tell the study doctor.
Complete Physical examination (1) /brief physical examination (including blood pressure, pulse rate (1)); Physical exam is an examination of certain body systems such as the heart and lungs. Blood pressure test measures the pressure in your arteries as your heart pumps. Pulse rate measures your heart rate by placing fingers near an artery to feel the beat of your heart.	Physical/brief physical examination risk: There are no known risks associated with a physical exam and pulse rate. Blood pressure risk: The test is usually painless, however as the blood pressure cuff squeezes your arm while it inflates it may be uncomfortable. This feeling lasts only a few seconds.
Safety laboratory tests (3); A blood sample will be taken to measure different analytes in your blood to determine if your levels are normal or abnormal and require therapy to treat a condition. Some laboratory tests have a fasting requirement which is going without food or liquids (other than water) for a certain number of hours. Some tests are only accurate if they are done after fasting.	Blood draw risk: A blood draw may cause faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight chance of infection. Fasting risk: could cause dizziness, headache, stomach discomfort, or fainting.
Illicit drug and alcohol use tests (3); urine, blood or breath tests will be taken to determine if you meet the requirements for the study.	Blood draw risk: as noted above
HIV and hepatitis blood tests (1); blood tests will be taken to determine if you meet the requirements for the study.	Blood draw risk: as noted above Other risk: the study doctor might be required to disclose the results of these tests to local health authorities, depending on the country in which you live and the local laws that apply.

The following is a list of the required study tests, procedures and assessments for this study, the number of times each is required and the item description (in parentheses):	**Associated risks are provided for the respective procedure/assessment:**
Pregnancy test (females only) (3); a urine or blood test to check for pregnancy.	Blood draw risk: as noted above
Follicle stimulating hormone test (females only) (1); a blood test to check for the hormonal level of females to confirm post-menopausal status.	Blood draw risk: as noted above
Contraception check (4); to confirm you are using the method and frequency stated at study entry or if this method has changed.	No known associated risk.
Electrocardiogram (3); is a test that records the electrical activity of the heart. A technician will place sticky patches on your chest, arms and legs that are connected by wires to a machine. These patches collect a signal that measures your heart activity.	The risks from an ECG can include skin irritation and a rash from the gel that is used or from wearing or removing the sticky patches.
COVID-19 status/SARS-CoV-2 RT PCR (1 and as needed); health assessment per local regulations obtained as part of health status.	Blood draw risk: as noted above
Study drug administration (1); fosmanogepix [redacted] mg or [redacted] mg (2 tablets of [redacted] mg) as a single oral dose will be prepared and administered by the CRU staff according to instructions provided by Basilea.	Potential side effects were described previously in this informed consent form.
Blood samples for pharmacokinetics (13); A blood sample will be taken to measure the amount of study drug in your blood. This sample may be used to determine how the study drug is changed and eliminated from your body after you take it. This sample may be also used to develop and/or evaluate the specific analysis method or for other internal exploratory purposes.	Fasting requirement and blood draw risk: as noted above
Blood sample for plasma protein binding (2); A blood sample will be taken to measure the degree to which the active study drug component attaches to proteins within the blood. This sample may be also used to develop and/or	Blood draw risk: as noted above

The following is a list of the required study tests, procedures and assessments for this study, the number of times each is required and the item description (in parentheses):	**Associated risks are provided for the respective procedure/assessment:**
evaluate the specific analysis method or for other internal exploratory purposes.	
Blood sample for genetics (1); a sample of your blood will be collected, stored, and used to learn more about the study drug in study participants with varying degrees of hepatic function. Biological substances in your sample(s), including your genes, may be studied. These samples may be kept by the Sponsor for as long as the samples are useful for scientific research, which may be for many years (no time limit).	Blood draw risk: as noted above. Genetics risk: This may include analyzing all your genetic information (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.
Concomitant medication/treatment reviews (9); medication taken that is not being studied in the clinical trial.	No known associated risk.
Adverse event (AE)/serious adverse event (SAE) check (9); An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. A SAE is defined as any untoward medical occurrence that, at any dose, meets one or more of the following criteria: death, life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, is a suspected transmission via a Sponsor product of an infectious agent, pathogenic or non-pathogenic, or medically significant events.	No known associated risk.
Follow-up phone call to check status (1)	No known associated risk.

APPENDIX B: TIMELINE GRAPHIC FOR PARTICIPANTS

Visit identifier	**Screen**	**CRU admission period**							**F/U**	**Early discont-inuation**
Days relative to Day 1	**Days −28 to −2**	**Day −1**	**Day 1**	**Day 2**	**Day 3**	**Day 5**	**Day 8**	**Day 11**	**Days 28-35**	
Hours after dose			0	24	48	96	168	240		
Informed consent	X									
CRU confinement		X	→	→	→	→	→	X		
CRU discharge								X		
Inclusion/exclusion criteria	X	X								
Child-Pugh classification	X									
Demography	X									
Body weight and height	X									
Medical/medication history	X	X								
COVID-19 testing/risk assessment		X								
Physical examination	X	X						X		X
Review concomitant medications/non-drug treatments	X	X	→	→	→	→	→	→	X	X
Contraception check/review	X	X						X	X	X
Alcohol and tobacco use testing	X	X								
Urine drug testing	X	X								
HIV, HBsAg, HBcAb, HCVAb	X									
FSH (postmenopausal females only)	X									
Urine or serum pregnancy test (WOCBP only)	X	X						X		X
Safety laboratory tests	X	X						X		X

Visit identifier	**Screen**	**CRU admission period**							**F/U**	**Early discont-inuation**
Days relative to Day 1	**Days −28 to −2**	**Day −1**	**Day 1**	**Day 2**	**Day 3**	**Day 5**	**Day 8**	**Day 11**	**Days 28-35**	
Hours after dose			0	24	48	96	168	240		
Single, *supine* 12-Lead ECG	X		X					X		X
Vital signs (*seated* BP and PR, temperature)	X		X					X		X
Study intervention administration			X							
Pharmacokinetic blood sampling			X	X	X	X	X	X		X
Unbound fraction blood sampling			X							
Retained Research Sample for genetics (Prep D1)			X							
Serious and non-serious AE monitoring	X	→	→	→	→	→	→	→	X	X