Subject Information and Study Informed Consent Form

Protocol title:	A Phase 1, randomized, single-center, double-blind, placebo-controlled study of fosmanogepix administered as single and multiple doses in healthy adult Chinese subjects
Protocol number:	FMGX-CP-109 (PART-1)
Sponsor:	Basilea Pharmaceutica International Ltd, Allschwil
Principal Investigator:	Yun Liu
Phone:	[redacted]
Additional contact(s):	
Address:	[redacted]

What should you know about this study?

You are invited to participate in a clinical research study sponsored by Basilea Pharmaceutica International Ltd, Allschwil (the 'Sponsor'). The Sponsor is providing funding to Yun Liu/Shanghai Xuhui Central Hospital to conduct the study.

The purpose of this study is to investigate the pharmacokinetics (the way the body absorbs, distributes, and eliminates a drug) and safety of fosmanogepix following a single dose and repeated doses (by intravenous infusion [into a vein] or orally) in healthy Chinese adults.

The study drug fosmanogepix is an investigational drug. This means that it is not approved for use. Up until 31 March 2024, fosmanogepix had been studied in 312 people in 11 studies.

This study has been reviewed and approved by the Ethics Committee of [redacted]

Your personal information will be protected during this study as described in the section called 'Processing of your personal data'.

Your participation in this study is voluntary. You can ask the study doctor or study team any questions you have before you decide whether you want to take part in this study. If you decide to take part, you will be asked to read and sign this informed consent form. You will get a signed copy to take home. This research study is different from, and does not replace, your regular medical care.

How many people will take part in this study?

There will be approximately 52 people taking part in this study (32 in PART-1 and 20 in PART-2), at one research site in China. If you participate in the study, you will join in PART-1.

How long will your participation last?

You will be in this study for a maximum of 64 days. You will need to visit the research site 4 times (1 screening visit, a 6-day period where you will remain at the clinical research unit from Day −1 to Day 5, and 2 outpatient visits), and have 1 follow-up phone contact to end the study 28–35 days after your study drug intake. While staying overnight in the clinical research unit, the study team will visit you throughout the day and you will not be able to leave the facility.

What treatment will you receive?

If you participate in the study you will be assigned by chance (like the flip of a coin) to receive either fosmanogepix (low dose or high dose) or placebo (in this document these are both called 'study drug') and either intravenously or orally. A placebo is neutral and does not contain any active ingredients.

This is a double-blind study, which means that nobody (including you, your study doctor, or the study team) will know which group you will be in. This is done to make sure that the study results cannot be influenced by anyone. However, if it is necessary in an emergency, your study doctor can quickly find out which study drug you are receiving.

The first part of the study is divided into two cohorts. If you are participating in Cohort 1, on Day 1 you will be asked to take [redacted] mg fosmanogepix, or [redacted] mg fosmanogepix, or placebo orally as tablets. If you are participating in Cohort 2, on Day 1 you will be asked to take [redacted] mg fosmanogepix, or [redacted] mg fosmanogepix, or placebo intravenously for 3

hours (one infusion). The study team will give you the study drug while you are at the site. If you receive the study drug as tablets, you should swallow the tablets whole and you should not manipulate or chew them.

How will you be selected for the study?

You will first be asked to sign this Informed Consent Form. If you sign this Informed Consent Form, the study will then begin with a screening visit, which is to find out if you meet all the requirements to take part in this study. If you do not meet the requirements, you will not be able to take part in the study, and the study doctor will explain why.

If you decide not to sign this Informed Consent Form you will not be able to take part in the study.

What are the study procedures?

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.

The details of these tests, procedures, and assessments are shown in Table 1 and Table 2, and are summarized below. If you would like more information about the tests and procedures or which procedures will be done at each study visit, please ask the study doctor or study team.

- You will be asked to give som personal information (such as year of birth, race, ethnicity, and sex).
- You will be asked questions about your health, including your medical history, and whether you are taking med cations, and if so, for how long.
- You will have a physical examination assessing your general appearance, head, ears, nose, mouth, skin, eyes, heart, chest, abdomen, height, and weight.
- Your vital signs will be recorded. This includes your blood pressure, body temperature, heart rate, respiratory rate (number of breaths), and oxygen saturation (amount of oxygen in your blood).
- You will have blood drawn for laboratory tests such as clinical chemistry (to assess how your organs are working) and hematology (to assess your blood cells). You will also have urine collected for laboratory tests to check your general health.

- You will have tests for non-prescription drugs (urine) and alcohol (urine or breath), both of which must be negative for you to take part in the study.
- You will be required to undergo HIV, hepatitis, and syphilis testing at the screening visit, all of which must be negative for you to take part in the study. The study doctor might be required to disclose the results of these tests to local health authorities.
- If you are a woman able to have a child, you must agree to use contraception during the treatment and observation period of the study, and for at least 28 days after the last dose of study drug. Following a negative pregnancy test result (blood or urine) at Screening, the study doctor will discuss with you the methods of birth control that you should use while you are in this study and will help you select the method or methods most appropriate for you. The study doctor will also review the birth control methods with you during the study visits. Pregnancy testing will be performed on Day −1 and Day 11, again if you discontinue from the study drug early, and also if a menstrual cycle is missed during the active study period. If you are pregnant you cannot take part in the study.
- If you are a postmenopausal woman, you may have blood drawn for testing to confirm your postmenopausal status.
- You will have electrocardiogram (ECG) tests to record the electrical activity of your heart.
- You will have blood drawn separately 15 times to measure the amount of study drug in your blood (see scheduled details in Table 2).
- You will have blood drawn another two times to measure the way in which the study drug behaves in your blood (see scheduled details in Table 2).
- You will be asked during the study whether you have experienced any changes in your health status since you signed this consent form.
- The study doctor will check if you are doing well 28 to 35 days after you last receive study drug. This can be done over the phone, but you may be asked to come to the research site for additional assessments.

Table 1 Schedule of Assessments

Visit identifier	Screening	Treatment and observation (from Day -1 to Day 11)						Follow-up	Early discontinuation
Days Relative to Day 1	**Day −28 to Day −2**	**Day −1**	**Day 1**	**Day 2–4**	**Day 5**	**Day 7**	**Day 11**	**Day 29 – 36**	
Read and sign this Informed Consent Form	X								
Overnight stay in research site		→	→	→	→				
Outpatient visit	X					X	X		X
Eligibility criteria	X	X							
Questions about your health	X								
Physical examination	X	X					X		X
Height and weight	X	X					X		X
Collect blood and urine for safety tests	X	X	X				X		X
Providing personal information	X								
Pregnancy test (urine or blood) for women who are able to have children	X	X					X		X
Discussion about contraception	X	X			X			X	X
Blood test for postmenopausal women	X								
Drug (urine) and alcohol (urine or breath) tests	X	X							
ECG to measure your heart's electrical activity	X		X				X		X
Vital signs	X		X				X		X
HIV, hepatitis, syphilis tests	X								
Questions about any medicines you have recently used	X	X	X	X	X	X	X	X	X
Study drug administration			X						
Blood samples to measure the amount of study drug in your blood			X	X	X	X	X		
Blood samples to measure the way the study drug behaves in your blood			X						
Discharge					X				
Questions about how you are feeling	X	→	→	→	→	→	→	X	X

Note: Procedures marked by "→" in Table 1 will be performed continuously during the indicated period. The follow-up will be 28–35 days after the last study drug dose.

Table 2 Blood samples to measure the amount of study drug in the blood

Study day	Day 1								Day 2		Day 3	Day 4	Day 5	Day 7	Day 11
Hours after study drug administration	**0**	**1**	**2**	**3**	**4**	**6**	**8**	**12**	**24**	**36**	**48**	**72**	**96**	**144**	**240**
Blood samples to measure the amount of study drug in your blood	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Blood samples to measure the way the study drug behaves in your blood	X			X											

What is expected from you?

You must:

- Be willing and able to follow all scheduled visits, instructions about the study drug, blood samples for laboratory tests, and other study procedures.
- Tell the study team if you have taken part in any other study during the past year, or are now taking part in any other study.
- Follow instructions from the study team and discuss all prescription and non-prescription medications, supplements, or vaccines with the study team before you take them.
- Notify the study team if you move, and provide your new contact information.
- Not take any medications that are prohibited in the study.
- If you are a woman who is able to have children, agree to use a highly effective birth control method during the study treatment and observation period and for at least 28 days after the last dose of study drug.
- Agree to be confined to the research site for 5 nights.
- Agree not to donate blood during the study until after the follow-up contact.
- Not have a history of alcohol dependence.
- On Day 1, fasting is required for at least 4 hours after starting study drug administration.
- Not eat or drink (except water) at least 4 hours before blood collection (except on Day 1, in which you must not eat or drink for at least 10 hours before blood collection.
- Not drink water for 1 hour before study drug administration (except water used to swallow oral study drug), and for 1 hour after oral dosing on Day 1 (noncaffeinated drinks except grapefruit or grapefruit-related citrus fruit juices are allowed with meals and the evening snack).
- Not drink red wine, or eat grapefruit, or grapefruit-related citrus fruits (e.g., Seville oranges, pomelos, fruit juices) from 7 days before the first dose of study drug until after collection of the last blood sample.
- While in the research unit, eat only meals provided by the research unit as standard meals.
- Not consume caffeine-containing products from 24 hours before the first dose of study drug until after collection of the last blood sample.

- Not drink alcohol from 24 hours before admission to the research unit until after collection of the last blood sample.
- Not use tobacco or other nicotine-containing products from 24 hours before the first dose of study drug until you leave the research unit.
- Not perform strenuous exercise (e.g., heavy lifting, weight training, calisthenics, aerobics) for at least 48 hours before each blood collection (walking at a normal pace is permitted).

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

What are the benefits of being in this study?

This study is for research purposes only. There will be no direct benefit to you from taking part, but information learned from the study may help other people in the future. While it is possible that the results of this study will be commercially exploited and/or patented, please note that you will not receive any benefit from this.

What are the risks and possible discomforts?

You may have side effects from the study drug or procedures used in this study, which might be mild or serious. You will be watched carefully for any side effects, and the study doctor may decide that you need additional procedures or medications to help manage any 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 a study procedure was not the cause.

Side effects of fosmanogepix

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

Up until 31 January 2025, fosmanogepix had been studied in more than 10 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 patients received fosmanogepix upon request by their treating physician to treat infections in cases where no other appropriate medication was available.

The completed clinical studies demonstrated a favorable safety profile.

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 tests, loss of contact with reality (delirium), head discomfort, and hot flush.

One patient treated 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 patient 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.

In human studies, 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 observed in the tissues of the liver.

There were also signs in animals 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 of, or lower than, those anticipated in humans.

Levels of manogepix (the active component of fosmanogepix) anticipated in humans 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 risk of 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[1]) with 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.

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 regular physical examinations to check your nervous system function for any changes.

Allergic reaction risks

Almost any drug has a potential risk of causing an allergic reaction, which (if not treated quickly) could become life-threatening. **If you think you have any of the following symptoms of a serious allergic reaction, if you are in the hospital, you should tell the study doctor immediately, if you are out of the hospital, you should see a doctor immediately or call an emergency number and contact your study doctor:** (serious) trouble breathing with/without (sudden) wheezing, cough, tightness in the chest, or swelling of the face, eyelids, mouth, lips, gums, tongue, throat, or neck. Other allergic reactions may include skin rash (which may get worse), itching all over the body, reddening of the skin or itchy red spots, feeling warm, hives, or blisters.

Risks related to study procedures

Blood-draw risks

When a sample of your blood is drawn, you may experience some temporary bleeding, discomfort, bruising, swelling, pain, redness and/or, in rare circumstances, infection or irritation, at the needle site. In addition, you may experience similar discomfort from the intravenous infusion of study drug.

[1] 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.

Risks related to the indwelling catheter that is placed for study drug administration

Administration of study drug through a vein in your arm has similar risks as described above for taking blood samples. You may also experience irritation or rash at the injection site, i.e., at the arm where the infusion is administered, and indwelling catheters may cause inflammation or become infected.

Electrocardiogram

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.

Other risks

There may be other risks that are currently unknown because fosmanogepix is still being developed.

Pregnancy-related risks

Fosmanogepix may cause harm to the fetus when administered to a pregnant woman (as seen in animal studies), and taking the study drug might also involve unknown risks to a pregnant woman, an embryo, unborn baby or nursing infant. Therefore, if you are pregnant, planning to become pregnant, or are breastfeeding, you cannot take part in this study. Before entering the study, two pregnancy tests (at Screening and on Day −1) will be done for all women who are able to become pregnant. Pregnancy tests (blood or urine) will also be repeated during the study. Women who are able to become pregnant must agree to use a highly effective birth control method during the study, and for at least 28 days after the last dose of study drug.

Because it is not known whether fosmanogepix passes into human breast milk, nursing mothers cannot par icipate in this study.

Pregnancy Follow-Up

If you become pregnant during the study or within 28 days after the last dose of study drug, you should tell the study doctor as soon as possible. The study drug will be stopped immediately. The study doctor or study staff will follow up your pregnancy until at least 8 weeks after delivery, or until the termination of the pregnancy.

What if there is new information about fosmanogepix?

If new information about fosmanogepix that would affect your safety and willingness to participate in the study is identified while you are in the study, you will be told as soon as possible, so you can decide whether to leave the study or continue. If you continue, you will be required to sign a new Informed Consent Form which includes the new information.

What are your options if you do not want to be in the study?

This study is for research purposes only. The alternative is not to take part in this study.

Will it cost you anything to be in this study?

You will not be charged for the study drug, and you will not have to pay for any study procedures.

Will you be paid if you join this study?

The estimated compensation amount for the single-dose group is CNY [redacted] per person, calculated as follows:

1) Blood sampling nutrition allowance: If you are eligible and participate in this trial, you can receive a nutrition allowance calculated at CNY [redacted] for each laboratory blood sample examination (1 screening check, 3 post-admission checks, a total of 4 times) and a nutrition allowance calculated at CNY [redacted] per blood sampling point during the trial period (At present, PK blood collection is tentatively scheduled for 15 times during the trial), totaling CNY [redacted]).

2) Transportation allowance and compliance compensation: If you complete the entire trial according to the trial requirements, in addition to the blood sampling nutrition allowance mentioned in item 1, you will receive an additional CNY [redacted] transportation allowance (CNY [redacted] per round trip, expec ed 4 times in total) and CNY [redacted]) as compliance compensation. If you fail to complete the trial as required (such as smoking, drinking alcohol, not undergoing timely examinations, not providing blood samples on time, etc.), a corresponding compliance fee will be deducted at the rate of CNY [redacted] per incident, and the research staff will decide whether you can continue to participate in the trial based on the circumstances

3) If you voluntarily withdr w from the trial due to personal reasons, or if the research staff asks you to withdraw due to poor compliance (such as failing to take medication or provide blood samples on time), you will still be entitled to receive the blood sampling nutrition allowance calculated based on the actual number of blood samples/times as mentioned in item 1, and the transportation allowance calculated based on the actual number of round trips as mentioned in item 2. If an adverse event occurs and the research doctor determines that withdrawing from the trial midway is in your best interest, you will still be entitled to receive the blood sampling nutrition allowance calculated based on the actual number of blood samples/times as mentioned in item 1, the transportation allowance calculated based on the actual number of round trips as mentioned in item 2, and a compliance compensation calculated proportionally based on the completed portion of the trial.

Additionally, the compensation for backup subjects is specified as follows:

Based on the screening order, you may be selected as a backup subject. Backup subjects may not necessarily be enrolled for drug administration. According to the protocol requirements, you need to check in one day before the drug administration, just like other subjects, and go through the admission procedures. Based on the inclusion/exclusion results before drug administration, you may be directly enrolled to participate in the formal trial. If you cannot be enrolled, you will leave the ward after the drug administration for other subjects is completed, and you will receive a compensation of CNY [redacted]). If you leave the ward on the day of admission, you will receive a compensation of CNY [redacted]).

You will be paid by bank transfer within three weeks of the end of the trial.

Can you leave the study after it has begun?

Your participation in this study is voluntary and 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 would like to stop the study drug so that you can end your participation in the safest way. It would be helpful if you could explain your reasons.

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

- If you are unable or unwilling to follow the instructions of the study staff.
- The study doctor decides that the study is not in your best interests, or that you are no longer eligible to be in the study.
- You become pregnant.

You may also stop bei g in the study at any time if it is stopped by the Sponsor, a government or regulatory authority, or by an Institutional Review Board (IRB) or Independent Ethics Committee (IEC) (a group of people who review the study to protect your rights).

If study drug is discontinued, your study doctor will ask you whether you agree to still participate in study assessments, in the form of an 'Early discontinuation' visit as shown in Table 1. If you agree, your study doctor will also ask you to be contacted by telephone for a 'Follow up' 28 to 35 days after your last study drug administration. Information about your health will continue to be collected and used as described in the study procedures section of this form, and in the privacy section, unless you specifically request your study doctor not to perform these study procedures, or you do not agree to be contacted to obtain further information about your health.

What treatment costs will be paid if you are injured in this study?

You will be given a study information card with information about your participation in the study. Please show this card to any healthcare provider if you need to seek emergency care during this study. The card contains information about the study that will help the healthcare provider treat you.

In the event that you are harmed or even die as a result of your participation in this clinical trial, sponsor and the insurance company will pay compensation in accordance with the relevant legal provisions, and corresponding costs such as lost wages and transportation expenses will also be paid.

You are not waiving any legal rights by signing this form, by accepting medical care, or by accepting payment for medical expenses.

What will happen with your biological samples?

You must provide biological samples (such as blo d or urine) in order to take part in this study. Additional samples may be collected depending on the results of your laboratory tests. A company hired by the Sponsor may be involved in the collection, transportation, or storage of these samples.

The total blood sampling volume collected from you during the study for measuring the amount of study drug in your blood and for measuring the way in which the study drug behaves in your blood will be approximately 84 mL. Other blood sampling volume for safety or other assessments depend on the study site clinical practice requirements. Additional blood samples may be taken for safety assessments at times specified by the Sponsor or study doctor, p ovided the total volume taken during the study does not exceed 550 mL during any period of 56 consecutive days.

Several different types of biological samples will be collected for the purpose of the study:

- Blood and urine samples (Blood sampling for safety or other assessments will be collected depending on the study site clinical practice requirements and expected to total about 50mL; urine will be collected 10 mL each time, expected to be collected up to 9 times, which is expected to total about 90mL)

The blood and urine samples will be collected and tested for eligibility and safety reasons, and will be destroyed once the tests are completed. These blood and/or urine samples collected during the study will be shipped to a local laboratory. These samples will be coded (so that your name will not appear on them), and the only personal information provided to the laboratory doing this work will be your gender and year of birth.

- Blood samples to determine the amount of study drug in your blood

Blood samples will be collected to check the blood levels of fosmanogepix and manogepix, which is the active moiety of fosmanogepix, in your body. These samples will be sent to a central laboratory located in China, without any of your personal data attached. These samples will be kept for up to 5 years after the study is completed, and then destroyed. You will not receive results of any of these tests.

- Blood samples to determine the way in which the study drug behaves in your blood

Blood samples will be collected to check the degree to which manogepix, which is an active moiety of fosmanogepix, attaches to proteins within your blood. These samples will be sent to a central laboratory located in China, without any of your personal data attached. These samples will be kept for up to 5 years after the study is completed, and then destroyed. You will not receive results of any of these tests.

You may request that your samples be destroyed at a y time; however any data already collected from the sample before such a request will still be used for this study.

Contact information and links to additional study information

The study team will address any questions, concerns, or complaints you may have before, during, and after you complete the study. If you have an urgent medical problem related to taking part in this study, experience ny side effects, or if you think you are injured or ill because of this study, it is important that you contact your study team immediately. Contact information for your study site and study doctor is listed on the first page.

If you have any questions about your rights as a study participant or would like to speak with someone not directly involved in the study, you may contact: **The Independent Ethics Committee** li ted below

Independent Ethics Committee Contact Information:

Contact Person: Ethics Committee of [redacted]

[redacted]

[redacted]

The IEC is a group of people who review research studies to protect the rights and welfare of study participants.

A description and a summary of the results of this clinical study may be available on http://www.ClinicalTrials.gov, the EU Clinical Trials Information System (CTIS), and other public registries and websites in accordance with applicable laws and regulations. These websites will not include information that can identify you. Information on the websites is available in English. The trial summary may be published on National Medical Products Administration (NMPA) website (http://www.chinadrugtrials.org.cn), you can navigate there to get more information.

The Sponsor will provide the study doctor with information about the study results when all participants have completed the study, but the Sponsor will not know your individual information in a way which could identify you, and you will not be identified in the results.

PROCESSING OF YOUR PERSONAL DATA

How and why will your personal information be used/processed?

Basilea Pharmaceutica International Ltd, Allschwil ('Basilea'), the study Sponsor, is acting as the data controller.

Your personal details and information from the study are processed in accordance with Personal Information Protection Law of the People's Republic of China (Effective since November 1st, 2021) and other laws and regulations which are designed to protect your privacy, including the China Good Clinical Practice Guidance.

This research study may be performed only by collecting and using your medical information/data. The collection of your data, including your coded medical information, and the further processing of your personal data in the context of this study is necessary and required for reasons of public interest in the area of public health and for scientific/pharmaceutical research purposes. As Sponsor of the study, Basilea is also legally obliged by applicable laws and regulations to carry out a range of activities that required the processing of your personal data; such activities include for example to report the results of the study to authorities and to the public, to perform safety reporting, or to archive the study data and medical files for up to 25 years after study completion depending on the country-specific record retention regulations unless local regulations or institutional policies require a longer retention period. Personal data will also be subject to mandatory inspections by health authorities during which personal data might be accessed by such authorities.

Your privacy is very important to us, and the Sponsor and study doctors will make every effort to protect it. Some of your health information, and/or information about any samples taken from you for this study, will be kept in a central database for research purposes.

Subject confidentiality is maintained as much as possible during and after the clinical study. To ensure confidentiality, a subject number (code) will be assigned to you once you have been enrolled in the study and you will only be identified by this number (and your birth year) and not for example by your name. We will do our best to make sure that your medical information will be kept confidential. However, absolute confidentiality cannot be guaranteed.

You will not be personally identified in any reports or publications that may result from this research study.

What information will be collected from you?

The study doctor and research team will collect, record, and use personal information about you for the study purposes. Your personal information collected during the study may include sensitive information about your physical or mental health or condition, and health information about you in medical records, and other personal information such as your name, address, telephone number, age, and gender. It may also include information related to the tests and procedures done in the study, and any blood or urine samples taken from you, or that you donate voluntarily during the study.

This study will also collect information about your race and ethnicity.

Your race and ethnicity are considered sensitive personal information under data protection laws. The results of this study will be grouped by race and ethnicity. This will help to decide if race and/or ethnicity affect if the study drug works and how safe it is in different populations. Your race and ethnicity will be collected and entered into the same database where the other data about you will be entered, stored, and protected during this study.

The medical information that will be collected from you if you participate in the study includes:

- Information obtained from procedures to determine your eligibility to participate in the study, including a routine medical history and prior and concomitant medication, physical examination, contraception measures, blood and urine tests, pregnancy tests, FSH test, drug and alcohol tests, HIV, HBsAg, HCVab, and HBcAg tests, height and weight assessments, ECG recordings, and vital sign measurements.
- Information that is created or collected from you during your participation in the study, including the result of the procedures listed above and any other procedures performed during the study.
- Information contained in your underlying medical records related to your medical history and treatment.
- Information about whether you are alive may be obtained from publicly available information in accordance with local law.
- In the event of pregnancy, general information on the pregnancy and its outcome (including general assessment of the baby at birth and within 8 weeks after birth) or the reason for termination.

As a part of this study, the study personnel may ask to see your healthcare records from your other healthcare providers.

How will your information be used?

If you sign this form and participate in the study, the study site personnel, the Sponsor, and the Sponsor's representatives will use the information described above to conduct the study. The study site personnel, the Sponsor, and the Sponsor's representatives will need to review the medical information collected from you to use in this study, in order to accurately record the information for study purposes.

Who will your information be given to?

All information that is collected about you in records that leave the study center for the purposes of medical, laboratory, statistical, or regulatory activities related to the study research will be identified by your subject code. Your full name or any other directly identifiable information about you will not be included in these records. Only the study doctor and study center will have access to information that can link you to your subject code; this information will not be shared outside of th study center unless necessary for safety purposes.

During the study, your collected personal information including your medical files may be disclosed to the Sponsor, its representatives assisting with the study research, including the local and central laboratories, study monitors, and to auditors, government or regulatory health authorities, and the Independent Ethics Committee. Your medical files may be reviewed at the study center (or study doctor's office) or remotely (outside of the study center) to check the information to verify the clinical study procedures, to evaluate the profile of the study drug in your blood, and to determine how safe the study drug is, without breaking your confidentiality. If your medical files are reviewed remotely, the records will include your subject code but will not include your name or other directly identifiable information.

Whether your medical files are reviewed at the study center or remotely for the purposes of the study, your records will be kept secure during this process.

Once your coded information is disclosed to the study Sponsor, its representatives, the IEC or regulatory agencies, there is a potential that your coded medical information will be re-disclosed and will no longer be protected by privacy laws which apply to the site/country where you will take part in the study. In addition to disclosures to the entities identified above, for the purposes of the study, the Sponsor or its representatives may provide your coded health information to others involved in the research study, including:

- Laboratories or offsite testing facilities for clinical tests required by the study protocol.

- Approved offsite storage facilities or cloud service providers to meet study record retention and storage requirements.
- Other third parties contracted by the Sponsor or its representatives to provide services related to the study.
- Under certain circumstances, information that identifies you by name may leave the study site in connection with the study and be sent to a service provider contracted by the Sponsor, to provide you with reimbursement, as allowed by applicable law, for certain expenses related to your participation. The service provider contracted by the Sponsor to provide this service must keep your personal information private, and they must not share with the Sponsor any information that can directly identify you.

Your information may also be disclosed if required by law. For example, some laws require doctors to report to health boards if they find a disease like tuberculosis. Unless required by law in such cases, the study doctor will only disclose information that will not identify you.

Other companies involved in the conduct of the tudy might be located in another country (e.g., laboratories, storage facilities, other companies contracted by the Sponsor or its representatives to provide services related to the study). While the Sponsor has put in place with all of these companies appropriate safeguards, and the companies have in turn put in place technical and organizational measures to protect your personal information, these other countries may not provide a level of protection of personal information comparable to the protection provided in the country where you will participate in the study. A copy of the details of the safeguards can be obtained from the Sponsor by writing to dataprotection@basilea.com.

Under Cyberspace Administration of China, the Cross-Border Data Transfer Security Assessment Measures in effect as of the 01 September 2022, and under the "Measurement", both Basilea and your study site will be considered "data controllers" in the context of the study. That means that Basilea and your study site have the responsibility to ensure that personal data collected in the course of the study must be processed in accordance with law. The study site will have that responsibility with respect to the study data which have been recorded in your medical record. Basilea will assume that responsibility with respect to the pseudonymized study data, which the study doctor transferred to Basilea or third parties.

BARDA certificate of confidentiality

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

This means that the staff of Basilea, Shanghai Xuhui Central Hospital and their subcontracts 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 in any action or suit unless you say it is okay.

A CoC protects your private information from all legal proceedings. Your information can't 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.

Informed Consent Form

By signing this Informed Consent Form, I agree to the following:

- I have read, and I understand, this Informed Consent Form.
- I have been given the chance to ask any questions that I had about the study, and all questions that I asked were answered to my satisfaction.
- I understand the risks of taking part in this study as described in this Informed Consent Form.
- I understand that there is no guarantee that I will receive any benefits from taking part in this study.
- I confirm that all information that I have given about my medical history is correct to the best of my knowledge.
- I understand that I will receive a copy of this signed and dated written Informed Consent Form.
- I understand that my participation in this study is voluntary, and that I am free to withdraw from the study at any time without giving any reason, and without my medical care or legal rights being affected
- I voluntarily agree to take part in this study.

Acknowledgement and consent to the processing of personal data

☐ I have read and understand the information provided in the section titled **Processing of your personal data**

, and acknowledge and consent that my personal data will be processed as described in this form.

You will be given a copy of this signed and dated consent form.

Name of participant (print)		
Signature of participant	Date of signature	Time of signature

Subject has no capacity for civil conduct, guardian signature is required; Subject is a person with limited capacity for civil conduct, Guardian and self signature is required.

Name of Guardian (print)

The Relationship between Subject and Guardian

Signature of Guardian	Date of signature	Time of signature

When the study participant or guardian is unable to read, the entire informed consent process should be signed and dated by an impartial witness.

Name of Impartial Witness (print)

Signature of Impartial Witness	Date of signature	Time of signature

Investigator statement for obtaining informed consent

- I have explained the additional procedures to the subject and answered all of his/her questions. I believe that he/she understands the information as described in this document, and freely consents to participate in the study.
- I will give the subject a copy of this signed and dated Informed Consent Form.

Name of investigator conducting the informed consent discussion (print)		
Signature of investigator conducting the informed consent discussion	Date of signature	Time of signature

Subject Information and Study Informed Consent Form

Protocol title:	A Phase 1, randomized, single-center, double-blind, placebo-controlled study of fosmanogepix administered as single and multiple doses in healthy adult Chinese subjects
Protocol number:	FMGX-CP-109 (PART-2)
Sponsor:	Basilea Pharmaceutica International Ltd, Allschwil
Principal Investigator:	Yun Liu
Phone:	[redacted]
Additional contact(s):	
Address:	[redacted]

What should you know about this study?

You are invited to participate in a clinical research study sponsored by Basilea Pharmaceutica International Ltd, Allschwil (the 'Sponsor'). The Sponsor is providing funding to Yun Liu/Shanghai Xuhui Central Hospital to conduct the study.

The purpose of this study is to investigate the pharmacokinetics (the way the body absorbs, distributes, and eliminates a drug) and safety of fosmanogepix following a single dose and repeated doses (by intravenous infusion [into a vein] or orally) in healthy Chinese adults.

The study drug fosmanogepix is an investigational drug. This means that it is not approved for use. Up until 31 March 2024, fosmanogepix had been studied in 312 people in 11 studies.

This study has been reviewed and approved by the Ethics Committee of [redacted].

Your personal information will be protected during this study as described in the section called 'Processing of your personal data'.

Your participation in this study is voluntary. You can ask the study doctor or study team any questions you have before you decide whether you want to take part in this study. If you decide to take part, you will be asked to read and sign this informed consent form. You will get a signed copy to take home. This research study is different from, and does not replace, your regular medical care.

How many people will take part in this study?

There will be approximately 52 people taking part in this study (32 in PART-1 and 20 in PART-2), at one research site in China. If you participate in the study, you will join in PART-2.

How long will your participation last?

You will be in this study for a maximum of 70 days. You will need to visit the research site 5 times (1 screening visit, a 12-day period where you will remain at the clinical research unit from Day -1 to Day 11, and 3 outpatient visits), and have 1 follow-up phone contact to end the study 28-35 day after your last study drug intake. While staying overnight in the clinical research unit, the study team will visit you throughout the day and you will not be able to leave the facility.

What treatment will you receive?

If you participate in the study, you will be assigned by chance (like the flip of a coin) to receive either fosmanogepix or placebo (in this document these are both called 'study drug') and either intravenously or intravenously then orally. A placebo is neutral and does not contain any active ingredients.

This is a double-blind study, which means that nobody (including you, your study doctor, or the study team) will know which group you will be in. This is done to make sure that the study results cannot be influenced by anyone. However, if it is necessary in an emergency, your study doctor can quickly find out which study drug you are receiving.

The second part of the study is divided into two cohorts. On Day 1, you will be asked to take [redacted] mg fosmanogepix or placebo intravenously for 3 hours twice a day (one infusion in the morning and a second infusion 12 hours after). On Days 2 and 3, you will receive once a day [redacted] mg fosmanogepix or placebo intravenously for 3 hours, then continue to receive a daily intravenous study drug from day 4 to day 7 (Cohort 3: [redacted] mg fosmanogepix or placebo) or switch to daily oral administration on Days 4 to Day 7 (Cohort 4: [redacted] mg fosmanogepix or placebo). The study team will give you each dose of the study drug while you are at the site. If you receive the study drug as tablets, you should swallow the tablets whole and you should not manipulate or chew them.

How will you be selected for the study?

You will first be asked to sign this Informed Consent Form. If you sign this Informed Consent Form, the study will then begin with a screening visit, which is to find out if you meet all the requirements to take part in this study. If you do not meet the requirements, you will not be able to take part in the study, and the study doctor will explain why.

If you decide not to sign this Informed Consent Form you will not be able to take part in the study.

What are the study procedures?

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.

The details of these tests, pro edures, and assessments are shown in Table 1 and Table 2, and are summarized below. If you would like more information about the tests and procedures or which procedures will be done at each study visit, please ask the study doctor or study team.

- You will be asked to give some personal information (such as year of birth, race, ethnicity, and sex).
- You will be asked questions about your health, including your medical history, and whether you are taking medications, and if so, for how long.
- You will have a physical examination assessing your general appearance, head, ears, nose, mouth, skin, eyes, heart, chest, abdomen, height, and weight.
- Your vital signs will be recorded. This includes your blood pressure, body temperature, heart rate, respiratory rate (number of breaths), and oxygen saturation (amount of oxygen in your blood).

- You will have blood drawn for laboratory tests such as clinical chemistry (to assess how your organs are working) and hematology (to assess your blood cells). You will also have urine collected for laboratory tests to check your general health.
- You will have tests for non-prescription drugs (urine) and alcohol (urine or breath), both of which must be negative for you to take part in the study.
- You will be required to undergo HIV, hepatitis, and syphilis testing at the screening visit, all of which must be negative for you to take part in the study. The study doctor might be required to disclose the results of these tests to local health authorities.
- If you are a woman able to have a child, you must agree to use contraception during the treatment and observation period of the study, and for at least 28 days after the last dose of study drug. Following a negative pregnancy test result (blood or urine) at Screening, the study doctor will discuss with you the methods of birth control that you should use while you are in this study and will help you select the method or methods most appropriate for you. The study doctor will also review the birth control methods with you during the study visits. Pregnancy testing will be performed on Day −1 and Day 22, again if you discontinue from the study drug early, and also if a menstrual cycle is missed during the active study period. If you are pregnant you cannot take part in the study.
- If you are a postmenopausal woman, you may have blood drawn for testing to confirm your postmenopausal status.
- You will have electrocardiogram (ECG) tests to record the electrical activity of your heart.
- You will have blood drawn separately 22 times to measure the amount of study drug in your blood (see scheduled details in Table 2).
- You will be asked during the study whether you have experienced any changes in your health status since you signed this consent form.
- The study doctor will check if you are doing well 28 to 35 days after you last receive study drug. This can be done over the phone, but you may be asked to come to the research site for additional assessments.

Table 1 Schedule of Assessments

Visit identifier	Screening	Treatment and observation (from Day -1 to Day 22)												Follow-Up	Early discontinuation
Days Relative to Day 1	**Day −28 to Day −2**	**Day −1**	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**	**Day 8 – 11**	**Day 13**	**Day 17**	**Day 22**	**Day 35 – 42**	
Read and sign this Informed Consent Form	X														
Overnight stay in research site		→	→	→	→	→	→	→	→	→					
Outpatient visit	X										X	X	X		X
Eligibility criteria	X	X													
Questions about your health	X														
Physical examination	X	X											X		X
Height and weight	X	X											X		X
Collect blood and urine for safety tests	X	X	X			X			X				X		X
Providing personal information	X														
Pregnancy test (urine or blood) for women who are able to have children	X	X											X		X
Discussion about contraception	X	X								X				X	X
Blood test for postmenopausal women	X														
Drug (urine) and alcohol (urine or breath) tests	X	X													
ECG to measure your heart's electrical activity	X		X			X			X				X		X
Vital signs	X		X			X			X				X		X
HIV, hepatitis, syphilis tests	X														
Questions about any medicines you have recently used	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Study drug administration			X	X	X	X	X	X	X						
Blood samples to measure the amount of study drug in your blood			X	X	X			X	X	X	X	X	X		X
Discharge										X					
Questions about how you are feeling	X	→	→	→	→	→	→	→	→	→	→	→	→	X	X

Note: Procedures marked by "→" in Table 1 will be performed continuously during the indicated period. The follow-up will be 28–35 days after the last study drug dose.

Table 2 Blood samples to measure the amount of study drug in the blood

Study day	Day 1			Day 2, 3, 6	Day 7								Day 8		Day 9	Day 10	Day 11	Day 13	Day 17	Day 22
Hours after study drug administration	**0**	**3 (End of first infusion on Day 1)**	**12 (Pre-dose of second infusion on Day 1)**	**0**	**0**	**1**	**2**	**3**	**4**	**6**	**8**	**12**	**24**	**36**	**48**	**72**	**96**	**144**	**240**	**360**
Blood samples to measure the amount of study drug in your blood	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

What is expected from you?

You must:

- Be willing and able to follow all scheduled visits, instructions about the study drug, blood samples for laboratory tests, and other study procedures.
- Tell the study team if you have taken part in any other study during the past year, or are now taking part in any other study.
- Follow instructions from the study team and discuss all prescription and non-prescription medications, supplements, or vaccines with the study team before you take them.
- Notify the study team if you move, and provide your new contact information.
- Not take any medications that are prohibited in the study.
- If you are a woman who is able to have children, agree to use a highly effective birth control method during the study treatment and observation period and for at least 28 days after the last dose of study drug.
- Agree to be confined to the research site for 11 nights.
- Agree not to donate blood during the study until after the follow-up contact.
- Not have a history of alcohol dependence.
- On Day 7, fasting is requir d for at least 4 hours after starting study drug administration.
- Not eat or drink (except water) at least 4 hours before blood collection at screening, Day -1, Day 22, and if you discontinue from the study drug early. In addition, on Day 7 you must not eat or drink for at least 10 hours before blood collection).
- Not drink water for 1 hour before study drug administration (except water used to swallow oral study drug), and for 1 hour after oral dosing on Day 7 (noncaffeinated drinks except grapefruit or grapefruit-related citrus fruit juices are allowed with meals and the evening snack).
- Not drink red wine, or eat grapefruit, or grapefruit-related citrus fruits (e.g., Seville oranges, pomelos, fruit juices) from 7 days before the first dose of study drug until after collection of the last blood sample.
- While in the research unit, eat only meals provided by the research unit as standard meals.
- Not consume caffeine-containing products from 24 hours before the first dose of study drug until after collection of the last blood sample.

- Not drink alcohol from 24 hours before admission to the research unit until after collection of the last blood sample.
- Not use tobacco or other nicotine-containing products from 24 hours before the first dose of study drug until you leave the research unit.
- Not perform strenuous exercise (e.g., heavy lifting, weight training, calisthenics, aerobics) for at least 48 hours before each blood collection (walking at a normal pace is permitted).

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

What are the benefits of being in this study?

This study is for research purposes only. There will be no direct benefit to you from taking part, but information learned from the study may help other people in the future. While it is possible that the results of this study will be commercially exploited and/or patented, please note that you will not receive any benefit from this.

What are the risks and possible discomforts?

You may have side effects from the study drugs or procedures used in this study, which might be mild or serious. You will be watched carefully for any side effects, and the study doctor may decide that you need additional procedures or medications to help manage any 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 a study procedure was not the cause.

Side effects of fosmanogepix

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

Up until 31 January 2025, fosmanogepix had been studied in more than 10 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 patients received fosmanogepix upon request by their treating physician to treat infections in cases where no other appropriate medication was available.

The completed clinical studies demonstrated a favorable safety profile.

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 tests, loss of contact with reality (delirium), head discomfort, and hot flush.

One patient treated 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 patient recovered.

In human studies, 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 observed in the tissues of the liver.

There were also signs in animals of temporary adverse effects on the nervous system, including shaking (trem rs). The levels of fosmanogepix in the animals' blood associated with these changes were in some cases at the levels of, or lower than, those anticipated in humans.

Levels of manogepix (the active component of fosmanogepix) anticipated in humans 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 risk of 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[1]) with 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.

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 regular physical examinations to check your nervous system function for any changes.

Allergic reaction risks

Almost any drug has a potential risk of causing an allergic reaction, which (if not treated quickly) could become life-threatening. **If you think you have any of the following symptoms of a serious allergic reaction if you are in the hospital, you should tell the study doctor immediately, if you are out of the hospital, you should see a doctor immediately or call an emergency number and contact your study doctor:** (serious) trouble breathing with/without (sudden) wheezing, cough, tightness in the chest, or swelling of the face, eyelids, mouth, lips, gums, tongue, throat, or neck. Other allergic reactions may include skin rash (which may get worse), itching all over the body, reddening of the skin or itchy red spots, feeling warm, hives, or blisters.

Risks related to study procedures

Blood-draw risks

When a sample of your blood is drawn, you may experience some temporary bleeding, discomfort, bruising, swelling, pain, redness and/or, in rare circumstances, infection or

[1] 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.

irritation, at the needle site. In addition, you may experience similar discomfort from the intravenous infusion of study drug.

Risks related to the indwelling catheter that is placed for study drug administration

Administration of study drug through a vein in your arm has similar risks as described above for taking blood samples. You may also experience irritation or rash at the injection site, i.e., at the arm where the infusion is administered, and indwelling catheters may cause inflammation or become infected.

Electrocardiogram

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.

Other risks

There may be other risks that are currently unknown because fosmanogepix is still being developed.

Pregnancy-related risks

Fosmanogepix may cause harm to the fetus when administered to a pregnant woman (as seen in animal studies), and taking the study drug might also involve unknown risks to a pregnant woman, an embryo, unborn baby, or nursing infant. Therefore, if you are pregnant, planning to become pregnant, or are breastfeeding, you cannot take part in this study. Before entering the study, two pregnancy tests (at Screening and on Day −1) will be done for all women who are able to become pregnant. Pregnancy tests (blood or urine) will also be repeated during the study. Women who are able to become pregnant must agree to use a highly effective birth control method during the study, and for at least 28 days after the last dose of study drug.

Because it is not known whether fosmanogepix passes into human breast milk, nursing mothers cannot participate in this study.

Pregnancy Follow-Up

If you become pregnant during the study or within 28 days after the last dose of study drug, you should tell the study doctor as soon as possible. The study drug will be stopped immediately. The study doctor or study staff will follow up your pregnancy until at least 8 weeks after delivery, or until the termination of the pregnancy.

What if there is new information about fosmanogepix?

If new information about fosmanogepix that would affect your safety and willingness to participate in the study is identified while you are in the study, you will be told as soon as possible, so you can decide whether to leave the study or continue. If you continue, you will be required to sign a new Informed Consent Form which includes the new information.

What are your options if you do not want to be in the study?

This study is for research purposes only. The alternative is not to take part in this study.

Will it cost you anything to be in this study?

You will not be charged for the study drugs, and you will not have to pay for any study procedures.

Will you be paid if you join this study?

The estimated compensation amount for the multiple-dose group is CNY [redacted] per person, calculated as follows:

1) Blood sampling nutrition allowance: If you are eligible and participate in this trial, you can receive a nutrition allowance calculat d at CNY [redacted] for each laboratory blood sample examination (1 screening check, 5 post-admission checks, a total of 6 times) and a nutrition allowance calculated at CNY [redacted] per blood sampling point during the trial period (At present, PK blood collection is tentatively scheduled for 22 times during the trial), totaling CNY [redacted] ([redacted]).

2) Transportation allowance and compliance compensation: If you complete the entire trial according to the trial requirements, in addition to the blood sampling nutrition allowance mentioned in item 1 you will receive an additional CNY [redacted] transportation allowance (CNY [redacted] per round trip, expected 5 times in total) and CNY [redacted]) as compliance compensation. If you fail to complete the trial as required (such as smoking, drinking alcohol, not undergoing timely examinations, not providing blood samples on time, etc.), a corresponding compliance fee will be deducted at the rate of CNY [redacted] per incident, and the research staff will decide whether you can continue to participate in the trial based on the circumstances.

3) If you voluntarily withdraw from the trial due to personal reasons, or if the research staff asks you to withdraw due to poor compliance (such as failing to take medication or provide blood samples on time), you will still be entitled to receive the blood sampling nutrition allowance calculated based on the actual number of blood samples/times as mentioned in item 1, and the transportation allowance calculated based on the actual number of round trips as mentioned in item 2. If an adverse event occurs and the research doctor determines that withdrawing from the trial midway is in your best interest, you will still be entitled to receive the blood sampling nutrition allowance calculated based on the actual number of blood samples/times as mentioned in item 1, the transportation allowance calculated based on the actual number of round trips as mentioned in item 2, and a compliance compensation calculated proportionally based on the completed portion of the trial.

Additionally, the compensation for backup subjects is specified as follows:

Based on the screening order, you may be selected as a backup subject. Backup subjects may not necessarily be enrolled for drug administration. According to the protocol requirements, you need to check in one day before the drug administration, just like other subjects, and go through the admission procedures. Based on the inclusion/exclusion results before drug administration, you may be directly enrolled to participate in the formal trial. If you cannot be enrolled, you will leave the ward after the drug administration for other subjects is completed, and you will receive a compensation of CNY [redacted]. If you leave the ward on the day of adm ssion, you will receive a compensation of CNY [redacted] ([redacted].

You will be paid by bank transfer within three weeks of the end of the trial.

Can you leave the study after it has begun?

Your participation in this study is voluntary and 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 would like to stop the study drug so that you can end your participation in the safest way. It would be helpful if you could explain your reasons.

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

- If you are unable or unwilling to follow the instructions of the study staff.
- The study doctor decides that the study is not in your best interests, or that you are no longer eligible to be in the study.
- You become pregnant.

You may also stop being in the study at any time if it is stopped by the Sponsor, a government or regulatory authority, or by an Institutional Review Board (IRB) or Independent Ethics Committee (IEC) (a group of people who review the study to protect your rights).

If study drug is discontinued, your study doctor will ask you whether you agree to still participate in study assessments, in the form of an 'Early discontinuation' visit as shown in Table 1. If you agree, your study doctor will also ask you to be contacted by telephone for a 'Follow up' 28 to 35 days after your last study drug administration. Information about your health will continue to be collected and used as described in the study procedures section of this form, and in the privacy section, unless you specifically request your study doctor not to perform these study procedures or you do not agree to be contacted to obtain further information about your health.

What treatment costs will be paid if you are injured in this study?

You will be given a study information card with information about your participation in the study. Please show this card to any healthcare provider if you need to seek emergency care during this study. The card contains information about the study that will help the healthcare provider treat you.

In the event that you are harmed or even die as a result of your participation in this clinical trial, sponsor and the insurance company will pay compensation in accordance with the relevant legal provisions, and corresponding costs such as lost wages and transportation expenses will also be paid.

You are not waiving any legal rights by signing this form, by accepting medical care, or by accepting payment for medical expenses.

What will happen with your biological samples?

You must provide biological samples (such as blood or urine) in order to take part in this study. Additional samples may be collected depending on the results of your laboratory

tests. A company hired by the Sponsor may be involved in the collection, transportation, or storage of these samples.

The total blood sampling volume collected from you during the study for measuring the amount of study drug in your blood will be approximately 88 mL. Other blood sampling volume for safety or other assessments depend on the study site clinical practice requirements. Additional blood samples may be taken for safety assessments at times specified by the Sponsor or study doctor, provided the total volume taken during the study does not exceed 550 mL during any period of 56 consecutive days.

Several different types of biological samples will be collected for the purpose of the study:

- Blood and urine samples (Blood sampling for safety or other assessments will be collected depending on the study site clinical practice requirements and expected to total about 70mL; urine will be collected 10 mL each time, expected to be collected up to 11 times, which is expected to total about 110mL)

The blood and urine samples will be collected and t sted for eligibility and safety reasons, and will be destroyed once the tests are completed. These blood and/or urine samples collected during the study will be shipped to a local laboratory. These samples will be coded (so that your name will not appear on them), and the only personal information provided to the laboratory doing this work will be your gender and year of birth.

- Blood samples to determine the amount of study drug in your blood

Blood samples will be collected to check the blood levels of fosmanogepix and manogepix, which is the active moiety of fosmanogepix, in your body. These samples will be sent to a central laboratory located in China without any of your personal data attached. These samples will be kept for up to 5 years after the study is completed, and then destroyed. You will not receive results of any of these tests.

You may request that your samples be destroyed at any time; however any data already collected from the sample before such a request will still be used for this study.

Contact information and links to additional study information

The study team will address any questions, concerns, or complaints you may have before, during, and after you complete the study. If you have an urgent medical problem related to taking part in this study, experience any side effects, or if you think you are injured or ill

because of this study, it is important that you contact your study team immediately. Contact information for your study site and study doctor is listed on the first page.

If you have any questions about your rights as a study participant or would like to speak with someone not directly involved in the study, you may contact: **The Independent Ethics Committee** listed below.

Independent Ethics Committee Contact Information:

Contact Person: Ethics Committee of [redacted]

[redacted]

The IEC is a group of people who review research stud es to protect the rights and welfare of study participants.

A description and a summary of the results of this clinical study may be available on http://www.ClinicalTrials.gov, the EU Clinical Trials Information System (CTIS), and other public registries and websites in accordance with applicable laws and regulations. These websites will not include information that can identify you. Information on the websites is available in English. The trial summary maybe published on National Medical Products Administration (NMPA) website (http://www.chinadrugtrials.org.cn), you can navigate there to get more information.

The Sponsor will provide the study doctor with information about the study results when all participants have completed the study, but the Sponsor will not know your individual information in a way which could identify you, and you will not be identified in the results.

PROCESSING OF YOUR PERSONAL DATA

How and why will your personal information be used/processed?

Basilea Pharmaceutica International Ltd, Allschwil ('Basilea'), the study Sponsor, is acting as the data controller.

Your personal details and information from the study are processed in accordance with Personal Information Protection Law of the People's Republic of China (Effective since November 1st, 2021) and other laws and regulations which are designed to protect your privacy, including the China Good Clinical Practice Guidance.

This research study may be performed only by collecting and using your medical information/data. The collection of your data, including your coded medical information, and the further processing of your personal data in the context of this study is necessary and required for reasons of public interest in the area of public health and for scientific/pharmaceutical research purposes. As Sponsor of the study, Basilea is also legally obliged by applicable laws and regulations to carry out a range of activities that required the processing of your personal data; such activities include for example to report the results of the study to authorities and to the public, to perform safety reporting, or to archive the study data and medical files for up to 25 years after study completion depending on the country-specific record retention regulations unless local regulations or institutional policies require a longer retention period. Personal data will also be subject to mandatory inspections by health authorities during which personal data might be accessed by such authorities.

Your privacy is very important to us, and the Sponsor and study doctors will make every effort to protect it. Some of your health information, and/or information about any samples taken from you for this study, will be kept in a central database for research purposes.

Subject confidentiality is maintained as much as possible during and after the clinical study. To ensure confidentiality, a subject number (code) will be assigned to you once you have been enrolled in the study and you will only be identified by this number (and your birth year) and not for example by your name. We will do our best to make sure that your medical information will be kept confidential. However, absolute confidentiality cannot be guaranteed.

You will not be personally identified in any reports or publications that may result from this research study.

What information will be collected from you?

The study doctor and research team will collect, record, and use personal information about you for the study purposes. Your personal information collected during the study may include sensitive information about your physical or mental health or condition, and health information about you in medical records, and other personal information such as your name, address, telephone number, age, and gender. It may also include information related to the tests and procedures done in the study, and any blood or urine samples taken from you, or that you donate voluntarily during the study.

This study will also collect information about your race and ethnicity.

Your race and ethnicity are considered sensitive personal information under data protection laws. The results of this study will be grouped by race and ethnicity. This will help to decide if race and/or ethnicity affect if the study drug works and how safe it is in different populations. Your race and ethnicity will be collected and entered into the same database where the other data about you will be entered, stored, and protected during this study.

The medical information that will be collected from you if you participate in the study includes:

- Information obtained from procedures to determine your eligibility to participate in the study, including a routine medical history and prior and concomitant medication, physical examination, contraception measures, blood and urine tests, pregnancy tests, FSH test, drug and alcohol tests, HIV, HBsAg, HCVab, and HBcAg tests, height and weight assessments ECG recordings, and vital sign measurements.
- Information that is created or collected from you during your participation in the study, including the results of the procedures listed above and any other procedures performed during the study.
- Information contained in your underlying medical records related to your medical history and treatment.
- Information about whether you are alive may be obtained from publicly available information in accordance with local law.

- In the event of pregnancy, general information on the pregnancy and its outcome (including general assessment of the baby at birth and within 8 weeks after birth) or the reason for termination.

As a part of this study, the study personnel may ask to see your healthcare records from your other healthcare providers.

How will your information be used?

If you sign this form and participate in the study, the study site personnel, the Sponsor, and the Sponsor's representatives will use the information described above to conduct the study. The study site personnel, the Sponsor, and the Sponsor's representatives will need to review the medical information collected from you to use in this study, in order to accurately record the information for study purposes.

Who will your information be given to?

All information that is collected about you in r cords that leave the study center for the purposes of medical, laboratory, statistical, or regulatory activities related to the study research will be identified by your subject code. Your full name or any other directly identifiable information about you will not be included in these records. Only the study doctor and study center will have access to information that can link you to your subject code; this information will not be shared outside of the study center unless necessary for safety purposes.

During the study, your collected personal information including your medical files may be disclosed to the Sponsor, its representatives assisting with the study research, including the local and central laboratories, study monitors, and to auditors, government or regulatory health authorities, and the Independent Ethics Committee. Your medical files may be reviewed at the study center (or study doctor's office) or remotely (outside of the study center) to check the information, to verify the clinical study procedures, to evaluate the profile of the study drug in your blood, and to determine how safe the study drug is, without breaking your confidentiality. If your medical files are reviewed remotely, the records will include your subject code but will not include your name or other directly identifiable information.

Whether your medical files are reviewed at the study center or remotely for the purposes of the study, your records will be kept secure during this process.

Once your coded information is disclosed to the study Sponsor, its representatives, the IEC or regulatory agencies, there is a potential that your coded medical information will be re-disclosed and will no longer be protected by privacy laws which apply to the site/country where you will take part in the study. In addition to disclosures to the entities identified above, for the purposes of the study, the Sponsor or its representatives may provide your coded health information to others involved in the research study, including:

- Laboratories or offsite testing facilities for clinical tests required by the study protocol.
- Approved offsite storage facilities or cloud service providers to meet study record retention and storage requirements.
- Other third parties contracted by the Sponsor or its representatives to provide services related to the study.
- Under certain circumstances, information that identifies you by name may leave the study site in connection with the study and be sent to a service provider contracted by the Sponsor, to provide you with reimbursement, as allowed by applicable law, for certain expenses related to your participation. The service provider contracted by the Sponsor to provide this service must keep your personal information private, and they must not share with the Sponsor any information that can directly identify you.

Your information may also be disclosed if required by law. For example, some laws require doctors to report to health boards if they find a disease like tuberculosis. Unless required by law in such cases, the study doctor will only disclose information that will not identify you.

Other companies involved in the conduct of the study might be located in another country (e.g., laboratories, storage facilities, other companies contracted by the Sponsor or its representatives to provide services related to the study). While the Sponsor has put in place with all of these companies appropriate safeguards, and the companies have in turn put in place technical and organizational measures to protect your personal information, these other countries may not provide a level of protection of personal information comparable to the protection provided in the country where you will participate in the study. A copy of the details of the safeguards can be obtained from the Sponsor by writing to dataprotection@basilea.com.

Under Cyberspace Administration of China, the Cross-Border Data Transfer Security Assessment Measures in effect as of the 01 September 2022, and under the "Measurement", both Basilea and your study site will be considered "data controllers" in the context of the study. That means that Basilea and your study site have the responsibility to ensure that personal data collected in the course of the study must be processed in accordance with law. The study site will have that responsibility with respect to the study data which have been recorded in your medical record. Basilea will assume that responsibility with respect to the pseudonymized study data, which the study doctor transferred to Basilea or third parties.

BARDA certificate of confidentiality

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

This means that the staff of Basilea, Shanghai Xuhui Central Hospital and their subcontracts 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 in any action or suit unless you say it is okay.

A CoC protects your private information from all legal proceedings. Your information can't 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 yo 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.

Informed Consent Form

By signing this Informed Consent Form, I agree to the following:

- I have read, and I understand, this Informed Consent Form.
- I have been given the chance to ask any questions that I had about the study, and all questions that I asked were answered to my satisfaction.
- I understand the risks of taking part in this study as described in this Informed Consent Form.
- I understand that there is no guarantee that I will receive any benefits from taking part in this study.
- I confirm that all information that I have given about my medical history is correct to the best of my knowledge.
- I understand that I will receive a copy of this signed and dated written Informed Consent Form.
- I understand that my participation in this study is voluntary, and that I am free to withdraw from the study at any time without giving any reason, and without my medical care or legal rights being affected
- I voluntarily agree to take part in this study.

Acknowledgement and consent to the processing of personal data

☐ I have read and understand the information provided in the section titled **Processing of your personal data**

, and acknowledge and consent that my personal data will be processed as described in this form.

You will be given a copy of this signed and dated consent form.

_____
Name of participant (print)

Signature of participant	Date of signature	Time of signature

Subject has no capacity for civil conduct, guardian signature is required; Subject is a person with limited capacity for civil conduct, Guardian and self signature is required.

Name of Guardian (print)

The Relationship between Subject and Guardian

Signature of Guardian	Date of signature	Time of signature

When the study participant or guardian is unable to read, the entire informed consent process should be signed and dated by an impartial witness.

Name of Impartial Witness (print)

Signature of Impartial Witness	Date of signature	Time of signature

Investigator statement for obtaining informed consent

- I have explained the additional procedures to the subject and answered all of his/her questions. I believe that he/she understands the information as described in this document, and freely consents to participate in the study.
- I will give the subject a copy of this signed and dated Informed Consent Form.

Name of investigator conducting the informed consent discussion (print)		
Signature of investigator conducting the informed consent discussion	Date of signature	Time of signature