DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
A Phase 1 Safety and Intrapulmonary Pharmacokinetics Study of
ZTI-01 (Intravenous Fosfomycin Disodium) in Healthy Adult Subjects
DMID# 16-0058
Version 8.0, 21SEP2020

CONCISE SUMMARY
The purpose of this study is to determine the safety of a study drug called ZTI-01 (intravenous fosfomycin disodium) and to determine how well this study drug gets from the blood into the lungs. Fosfomycin is an antibiotic that is already available in oral form to treat serious urine or kidney infections. It may be able to treat serious pneumonias that are resistant to other common antibiotics.

If you agree to participate, you will stay at Duke for three days, during which you will receive three doses of the study drug with close monitoring of your medical status before and after all of the doses. You will have your blood drawn multiple times during the study to determine the blood levels of the drug, and to determine whether it has caused any side effects. After the third dose, you will undergo a bronchoscopy, which is a procedure to look at your lungs and air passages by inserting a tube through your mouth and down your throat to reach your lungs. This is done under conscious sedation to obtain samples from inside your lungs. After you leave Duke, you will be called the next day to find out how you are doing and after that call your participation in the study will be over.

If you participate, there will be no direct benefit to you. There are risks involved in receiving an experimental drug. In prior studies of ZTI-01, some participants had decreased heart rate or blood pressure, headaches, stomach upset, and changes in some of their blood lab values. There are also risks involved in having your blood drawn (like pain) and in undergoing bronchoscopy (like coughing and discomfort). These risks will be discussed in more detail below.

You are being asked to take part in this research study as a normal, healthy, adult volunteer. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Funding from the National Institutes of Health (NIH) will sponsor this study. Portions of [redacted] and their research team's salaries will be paid by this funding.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, [redacted] and [redacted] will be your doctors for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

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WHY IS THIS STUDY BEING DONE?

This is a study of an investigational drug, ZTI-01. *Investigational* means that it is a study drug, still being tested in research studies and not approved by the United States Food and Drug Administration (FDA). ZTI-01 is intravenous fosfomycin disodium. *Intravenous*, or IV for short, refers to a way of giving a drug or other substance through a catheter inserted into a vein.

Fosfomycin is an antibiotic and was approved by the FDA in 1996 in an oral form (meaning taken by mouth), at a lower dose, to treat urinary infections. ZTI-01 is an intravenous (IV) form of fosfomycin that may be able to treat serious pneumonia infections that are resistant to most available antibiotics. The IV form of fosfomycin is approved for use outside the United States (in Europe and Japan) and has been tested in people in other studies in the U.S., but is not approved by the U.S. FDA.

There are two main purposes of this study. The first is to understand the safety and side effects of this dosing regimen of ZTI-01 in healthy people. The second is to measure how well the study drug gets into the bloodstream and the lungs, and how long it lasts in each place.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 125 people will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?

Participation in this study is completely voluntary, and if you decide not to participate there will be no penalty or loss of benefits to which you are otherwise entitled.

If you agree to be in this study, you will be asked to sign and date this consent form. You will have the following tests and procedures to make sure that you are eligible:

- Physical exam and medical history
- Vital signs, height, and weight
- Blood (about 2 tablespoons will be drawn) and urine tests
- Breath test to detect alcohol
- Electrocardiogram (EKG), a tracing of the electrical activity of the heart

As part of this eligibility testing, you will be tested for COVID-19 (SARS-CoV-2). You will be notified of the results of the testing, and counseled as to the meaning of the results, whether they are positive or negative. If the test indicates that you are infected with COVID-19, you will receive additional counseling about the significance of your care and possible risks to other people. We are required to report all positive results to the North Carolina Division of Public Health. The test results will be kept confidential to the extent permissible under the law. If you do not want to be tested for COVID-19, then you should not agree to participate in this study.

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As part of this eligibility testing, you will be tested for HIV (human immunodeficiency virus, which is the virus that causes the acquired immunodeficiency syndrome [AIDS]). You will be notified of the results of the testing, and counseled as to the meaning of the results, whether they are positive or negative. If the test indicates that you are infected with HIV, you will receive additional counseling about the significance of your care and possible risks to other people. We are required to report all positive results to the North Carolina Division of Public Health. The test results will be kept confidential to the extent permissible under the law. If you do not want to be tested for HIV, then you should not agree to participate in this study.

If you are eligible and you agree to participate, we will schedule a time for you to come to Duke for an admission period of three days. During that admission period, you will be required to stay inside the unit but you will be free to walk around, and there will be television and games for your entertainment. Food will be provided during your stay except during the period of time when you will need to fast (not eat) prior to the bronchoscopy. You will be randomized to a specific time for your bronchoscopy procedure; the time assignments will be random, like drawing numbers out of a hat.

You will be asked to avoid non-prescription medications, vitamins, dietary or herbal supplements, caffeine, and consumption more than twice per week of products containing genuine licorice for 7 days prior to the admission period, and to avoid alcohol for 48 hours prior to the admission period.

If you are a female of childbearing potential, you will have a urine pregnancy test the day you come in for admission. You must use an acceptable contraceptive method for 30 days prior to the first dose of the study drug and for at least 30 days after the last dose of the study drug. The study team will discuss the acceptable methods with you.

If you are a male whose partner is of childbearing age, you must be willing to use condoms throughout the study, including for a full day after you leave the confinement unit.

When you come to Duke for your admission period, you will stay for three days. Before being given any of the study drug, you will have the following tests and procedures:

- Physical exam and medical history
- Vital signs and weight
- Blood (just under 2 teaspoons will be drawn) and urine tests
- Breath test to detect alcohol
- COVID-19 test (SARS-CoV-2)
- Placement of two peripheral IV lines in your veins, most likely one in each of your arms

Then, you will have the following procedures and tests over the course of one to two days:

- You will be given the study drug through your IV, one dose every eight hours for a total of three doses

- Vital signs (like blood pressure, temperature, heart rate, oxygen level) before, during, and several times after each dose
- EKG before the first dose and after the last dose of study drug
- Blood draws 18 different times before, during, and after the doses of the study drug; a total of just under 6 tablespoons of blood will be drawn
- Bronchoscopy either during or after the last dose of study drug, depending on your time assignment
- Urine tests after the last dose of study drug
- Physical exam and measurement of weight before leaving the admission unit

A bronchoscopy is an exam of the lungs using a long tube with a light on the end, which will be passed through your nose or mouth into your breathing tubes and lungs. Once it is in your lungs, a small amount of sterile saline solution will be squirted into a localized area of one of your lungs, then suctioned back up through the bronchoscope, and that fluid will be used for testing. Before the exam begins, medicines will be given through your IV to make you relaxed and sleepy. The drugs used most often are fentanyl and midazolam. This is a routine part of this exam. Lidocaine, a numbing medicine, will also be sprayed into your mouth, throat, and lungs. The bronchoscopy itself usually takes around 10 minutes. It may take longer than that to gradually give you the sedation medicine, and to allow you to wake up from the sedation.

The day after your bronchoscopy, you will be called by phone to ask about how you feel and any new medicines you are taking. If you are not having any concerning symptoms or complaints, your participation in the study will end after the follow-up phone call. If you are having any concerning symptoms or complaints, or if there are abnormalities with the testing that was done during the admission period, you may be asked to return to Duke for evaluation. In that case, your participation in the study will end when the symptoms or abnormalities are resolved or no longer require medical follow-up.

If you begin the study but choose not to continue or complete it for any reason, or if the study doctors determine that you should not continue or complete the study, then you will have the following procedures and tests before you leave the admission unit. This is for your safety, to check for any side effects of the drug:

- Physical exam and weight measurement
- Blood (about 1 tablespoon will be drawn) and urine tests

If there are no abnormalities observed on these procedures and tests, then your participation in the study will end at that time. If, however, there are abnormalities that the study doctors believe to be significant to your health, then additional follow-up visits may be scheduled so that you can be monitored appropriately.

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The total amount of blood drawn for this study will be up to 122.4 ml (about 8 tablespoons).

HOW LONG WILL I BE IN THIS STUDY?
You will be in the study from the time that you are found to be eligible and agree to participate, which could be up to 30 days before the admission period. Within those 30 days, you will be asked to avoid non-prescription medications, vitamins, dietary or herbal supplements, caffeine, and consumption more than twice per week of products containing genuine licorice for just the 7 days prior to the admission period, and to avoid alcohol for just the 48 hours prior to the admission period. The admission period for this study is three days. Then, you will continue in the study for one day after the admission period, up until the time that you receive the follow-up phone call. If significant abnormalities develop after you receive the study drug, then you may need to follow up with the study doctors until those abnormalities resolve or become stable.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to the study doctor [redacted] first.

WHAT ARE THE RISKS OF THE STUDY?
The risks of this study include side effects of the study drug itself, risks of the procedures that are done as part of the study, and the potential risk of loss of confidentiality.

Risks of the Study Drug
If you participate in the study, you may be at risk for the following side effects of ZTI-01. You should discuss these with the study doctor and your regular health care provider if you choose. ZTI-01 may cause some, all, or none of the side effects listed below.

More Likely

- Headache
- Decreased blood calcium (could cause muscle cramps, confusion, stiff achy muscles, tingling of lips, fingers and feet)
- Increased liver enzymes (could cause easy bruising, enlargement of abdomen, fluid retention)
- Decreased blood potassium (could cause weakness or, in extreme cases, abnormal heart rhythm)
- Decreased blood phosphorus (could cause weakness or, in extreme cases, confusion, trouble breathing, or trouble swallowing)
- Stomach upset, including nausea, vomiting, or diarrhea
- Swelling and pain at the IV site
- A change in your electrocardiogram (EKG, an electronic snapshot of the heart's electrical activity) called a prolonged QT interval, which usually does not cause any symptoms or problems but, in very rare or severe cases, can potentially cause fast or erratic heart beats

Less Likely

- Decreased blood pressure (could cause dizziness or weakness)
- A severe form of diarrhea called colitis that is known to occur with nearly any antibiotic medicine
- Allergic reactions, including rash, face or mouth swelling, or anaphylaxis, which is a severe and potentially life-threatening allergic reaction
- Kidney injury
- Liver injury
- Decreased appetite or change in the way things taste
- Dizziness or spinning sensation (vertigo)
- Shortness of breath or asthma attack
- Fatigue or confusion
- Vision changes
- Rapid heart rate
- Swelling in legs or body
- Increased blood sodium (could cause thirst or, in extreme cases, confusion)
- Decreases in the red blood cells, white blood cells, or platelets, which can, respectively, lead to fatigue or shortness of breath, risk of fever or infection, or risk of bleeding

You will be monitored closely for all of the above risks and appropriate medical care will be provided in the event that any of them occur.

Drug and Food Interactions
For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, products containing genuine licorice, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study.

Risks of Blood Draws and IV Insertion
Risks associated with drawing blood from your arm and/or inserting an IV line include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Risks of EKG
Possible side effects of the EKG are skin irritation, itching and redness from the EKG electrode pads.

Risks of Bronchoscopy

Although the bronchoscopy exam is not painful, common side effects are throat numbness, cough, and a sore throat. Some people experience brief gagging. Fevers or chills may occur after the bronchoscopy. Rarely, there can be chest pain, cough with phlegm containing blood, nosebleed, and temporary vomiting. The lidocaine liquid or spray to numb your mouth and throat has an awful taste and causes a strange feeling in the mouth. It can make you have trouble swallowing for 30-60 minutes after the bronchoscopy, so you will not be allowed to eat or drink during that time. Finally, any invasive procedure like bronchoscopy can result in stress on the heart or lungs.

The bronchoscopy exam includes moderate sedation, which is the use of drugs to make you relaxed and sleepy. The drugs used most often are fentanyl and midazolam. Midazolam may cause some people to feel drowsy, tired, or weak for 1 or 2 days after it has been given. It may also cause problems with using your hands or feet and your ability to think. Midazolam may make you dizzy, cause headache, low oxygen levels and low blood pressure. *Common* side effects of fentanyl are feeling dizzy, faint, or lightheaded, feeling tired or weak or having a hard time catching your breath or feeling out of breath. L*ess common* side effects are feeling anxious, confused, decrease in the amount of urine you make and the number of times you urinate; having to urinate less, feeling drowsy, nervous, having a false sense of well-being, and seeing, hearing, or feeling things that are not there. *Do not drive, use machines, sign legal documents, or do anything else that could cause you or someone else harm if you are not alert* until the effects of these drugs have gone away or until the day after you receive this drug, whichever period of time is longer. You will be watched closely during the bronchoscopy exam and we will treat you if any of these side effects occur. If you are scheduled to leave the confinement unit on the same day as your bronchoscopy exam, someone will need to drive you home. Otherwise, you will be welcome to stay an extra night in the confinement unit so that the effects of the sedative drugs have fully worn off.

To protect against these risks, you will be given oxygen and your vital signs and heart rhythm will be monitored continuously during the bronchoscopy. The doses of all medications given to you for bronchoscopy will be carefully monitored, with safe limits set. Care and monitoring will be provided before, during, and after the bronchoscopy by nursing staff with oversight by the study doctors.

Risk of Loss of Confidentiality
Every effort will be made your keep your information confidential; however, this cannot be fully guaranteed.

Reproductive Risks
For women: The effects of the study drug on a developing pregnancy or breastfeeding infant are unknown. Therefore, women who are pregnant, planning a pregnancy, or breastfeeding are excluded from this study.

If you are a woman who could possibly become pregnant (you have not completed menopause, or you have not had a hysterectomy and/or both tubes and/or both ovaries removed) and you have a partner who is able to father children, a blood pregnancy test will be done (using 1 teaspoon of blood drawn

from a vein by needle-stick), and it must be negative before you can continue in this study. In women 40 years old and older, blood pregnancy tests may sometimes give a false positive or indeterminate result, and additional testing may be required. A urine pregnancy test will also be performed the day of your admission.

You and your partner must agree to either abstain completely from vaginal intercourse for the duration of the study and for 30 days after discharge, or agree to use an effective method of contraception for the same length of time. Effective methods include (a) partner vasectomy, (b) bilateral tubal ligation, (c) intrauterine devices (IUDs), (d) hormonal methods (birth control pills, implants, injections, patches, vaginal rings, or (e) barrier methods (condoms, diaphragms, cervical caps) when used with a spermicide. If you are not using one of these methods, your doctor will discuss options with you, given your medical condition, your personal preferences, and the level of protection required by this study. Because no method is 100% effective, you should notify your study doctor immediately if you think there is any chance you could be pregnant.

For men: The effects of the study drug on developing pregnancies that began while the father was taking the drug are not known. In addition, the drug may be transmitted in semen to a partner during sexual activity. If your partner is a woman who could possibly become pregnant (she has not completed menopause, or has not had a hysterectomy and/or both tubes and/or both ovaries removed), you and your partner must agree to either abstain completely from vaginal intercourse for the duration of the study and until the follow-up phone call the day after your bronchoscopy, or use condoms each time you have vaginal intercourse for the same length of time. This is true even if you have had a vasectomy (because vasectomy does not prevent transmission of drug in seamen). If your partner is currently pregnant or breastfeeding, you must use a condom for all types of sexual activity. You should inform your partner about the possible risks of this study, and that you will need to report a pregnancy that occurs during the study to your study doctor.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there will be no direct medical benefit to you. We hope that in the future the information learned from this study will benefit other people with infections caused by bacteria that are resistant to common antibiotics.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum

necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related laboratory tests and procedures may be reported to the NIH and its affiliates, but this would be without the inclusion of any information that identifies you. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, representatives and affiliates of the NIH, the Duke University Health System Institutional Review Board, the company that manufactures the study drug, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. 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 consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

All of the blood, urine, bronchoscopy and EKG studies are being done only because you are in this study. The study results will not be provided to you OR sent to your physician.
Your information and samples that are collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

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We are required to report all positive results of the HIV test to the North Carolina Division of Public Health. The test results will be kept confidential to the extent permissible under the law. If you do not want to be tested for HIV, then you should not agree to participate in this study.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

A representative from the sponsor may be present at certain study visits/procedures.

WHAT ARE THE COSTS TO YOU?
There will be no cost to you associated with taking part in this study.

WHAT ABOUT COMPENSATION?
You will be reimbursed up to $1225 for your expenses related to your participation (parking, gas, and time). You will receive $100 for the screening visit, $250 for Day -1 visit, $250 for Day 1 visit, $600 for the Day 2/Bronchoscopy visit and $25 for the follow-up phone call visit.

Payment received as compensation for participation in research is considered taxable income to the research subject. If payment to an individual exceeds $600 in any one calendar year, Duke University is required to report this information to the Internal Revenue Service (IRS). Research subject payments to a non-employee of Duke University exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

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WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., your Duke physicians, or NIH to provide monetary compensation or free medical care to you in the event of a study-related injury. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the Federal Government.

For questions about the study or research-related injury, contact [redacted] at [redacted] or [redacted] at [redacted] during regular business hours. After-hours, [redacted] and [redacted] can both be reached through the Duke University Hospital operator at [redacted]

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact [redacted] or [redacted] in writing and let him/her know that you are withdrawing from the study. [redacted] mailing address is [redacted] and [redacted] mailing address is [redacted].

If you have already received study drug before withdrawing from the study, [redacted] or [redacted] may ask you to complete the tests that would ordinarily occur when a person completes the study, including a physical exam, questionnaires about how you feel, blood and urine tests.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. This might occur if other study participants experience bad effects. If your study doctor becomes aware of any new information that could change the safety of the study drug or your participation in the study, he or she will make you aware of that information and allow you to decide whether you wish to continue your participation.

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A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact [redacted] or [redacted] during regular business hours. After-hours, [redacted] can both be reached through the Duke University Hospital operator at [redacted]

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at [redacted]

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time