

INFORMED CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Study Title: A Phase I Open Label Study To Evaluate The Safety, Tolerability, And Pharmacokinetics Of Intravenous Dalbavancin in Subjects With Mild, Moderate, and Severe Hepatic Impairment and Healthy Subjects with Normal Hepatic Function

Sponsor: Versicor, Inc.
455 South Gulph Road
King of Prussia, PA 19406

Protocol No.: VER001-12

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24-Hour Telephone Number: [REDACTED]

INTRODUCTION

The following information describes the study and your role as a participant. This document is intended to inform you about the nature and risks of the clinical study in which you have been asked to participate. The study doctor or his designee will answer any questions you may have about this consent form and about the study. Please read this consent form carefully and do not hesitate to ask any questions you may have about the information provided below or about any words that you may not understand.

DESCRIPTION AND PURPOSE OF THE STUDY

You have been invited to participate in a clinical research study because you are either a volunteer with impaired liver function or have normal liver function. The research study involves dalbavancin, an investigational drug. "Investigational" means that the drug being tested has not been approved by the United States Food and Drug Administration (FDA) as a prescription or over-the-counter medicine, but may be tested in research studies such as this one. This study is sponsored by Versicor, Inc.

The number of bacterial infections that are resistant to currently available antibiotics is increasing. These types of infections can be especially dangerous to individuals who have weakened immune systems and/or who are hospitalized. Versicor, Inc. is developing a new antibiotic, known as dalbavancin, which may be effective against a variety of bacterial infections that are difficult to treat. The purpose of this study is to determine if dalbavancin is safe and well tolerated and to calculate how volunteers with impaired liver function and healthy volunteers with normal liver function absorb, breakdown and eliminate dalbavancin. In addition, information about any side effects that may occur will also be collected. This study is for research purposes only and is not designed to treat a medical condition.

This study is being conducted at approximately 2 centers in the United States and will involve approximately 36 subjects. Approximately 18 subjects will participate at the Orlando Clinical Research Center.

STUDY DURATION

You will make one screening visit within 21 days of entering the study. If you qualify, you will take part in the study for approximately 60 days. The study procedures require that you complete one 2 day/2 night clinic confinement followed by 7 outpatient visits (one of which will require you to remain at the clinical

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research center for approximately 13 hours). In addition, you will be required to have 2 Audiology (hearing) assessments one at the beginning of the study and one at the end.

STUDY PROCEDURES

If you agree to participate in this research study, you must sign this consent form before having any study-related tests or procedures performed.

To be in this study, you must be 18 – 80 years of age. The study staff will ask you questions about your health and medical history, your medication history in the previous 3 months and if you are currently taking any medications, (over-the counter or prescription) or vitamins.

Volunteers for this study must meet certain requirements. Since this is a study of an investigational drug, it is important to answer all questions honestly and to tell the study staff your complete health history.

If you are a woman who is able to become pregnant, you must have a negative pregnancy test at the Screening Visit and check-in. Women will only be allowed to enter this study if they are using contraception for at least one month prior to the study and agree to continue using it for six weeks after the last dose of study medication. Acceptable forms of birth control include (either oral contraception **plus** barrier contraceptive, IUD, condoms with spermicide or diaphragm with spermicide), are surgically sterile (have undergone a bilateral tubal ligation, removal of both ovaries, or total hysterectomy), or are postmenopausal (at least 1 year without periods).

SCREENING VISIT

Once you have consented to participate in this study you must undergo the following screening procedures.

You will be asked about your medical/surgical history in the previous 3 months and about any medications including over the counter medications and vitamin supplements you have taken in the previous 30 days and/or are currently taking. You will also be given a physical examination including height, weight and vital signs (heart rate, temperature, and blood pressure). You will be given a drug screen to test for drug and/or alcohol abuse. Urine will be collected and blood (about 1 tablespoon) will be drawn for laboratory tests. The blood and urine will be used to evaluate blood counts and chemistries. If you are a female of childbearing potential, some of the blood sample will be for pregnancy testing.

In addition, you will have an electrocardiogram (ECG, electrical tracing of heart activity) to evaluate your heart rhythm and you will have standard hearing tests performed by an audiologist (a person trained in hearing and balance disorders) to evaluate your hearing function.

If the procedures and test results indicate that you are eligible for this study, you will be notified and admitted to the clinical research center the evening (Day -1). You will be asked about any new medical/surgical history and any medication you have taken since the screening visit. You will have your vital signs taken. If you are a female of childbearing potential, blood will be drawn for a repeat pregnancy test.

Admittance to the study is not final until all laboratory tests that were performed at screening and/or check-in have been returned and judged to be satisfactory by the study doctor.

TREATMENT PERIOD

On Day 1, two catheters (small plastic flexible tubes with special needle device designed to be placed into a vein and remain in the vein over a period of time) will be placed one in each arm. The catheter will allow the study personnel to administer the study drug through one tube and obtain blood samples from the other and to decrease the number of needle stick necessary for blood sampling. Before study medication is given, blood samples will be drawn and vital signs will be taken. You will receive a single dose of 1000mg of Dalbavancin (study drug) through one of the catheters in your arm over 30 minutes. The catheter will be inspected, maintained and may be changed if necessary during the clinic confinement.

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Blood samples will be taken to measure the levels of the study drug in your blood at the end of infusion, 4 and 12 hours after the start of infusion. Additional blood samples will be taken to measure blood levels of the study drug on Day 2 at approximately the same time that the study drug was started on Day 1. Your blood pressure, pulse, respiration, and temperature will be taken periodically. A 12-lead ECG (test to evaluate your heart rhythm) will be taken shortly after the completion of the study drug infusion. Blood will be drawn and urine collected on Day 2 for laboratory testing. You will go home on Day 2 after blood and urine samples are drawn and all procedures have been completed. You will be given instructions when to return to the clinic for out patient visits.

OUT PATIENT VISITS

You will return to the clinical research center on days 4, 8, 11, 15, 22, 29, and 60. At each visit, you will be asked about any symptoms or illnesses that you may have experienced. In addition, you will be asked to inform the investigator and/or study staff of any medications or therapies you are taking while you are participating in this study.

On Day 4, blood samples will be taken at approximately the same time that the study drug was started on Day 1. Blood will be drawn and urine collected on Day 4 for laboratory testing.

On Day 8 you will report to the clinical research center and remain for approximately 13 hours. Two catheters (small plastic flexible tubes) will be inserted into your vein, one in each arm. The catheter will allow the study personnel to administer the study drug through one tube and obtain blood samples from the other. Before study medication is given, blood samples will be drawn. You will receive a single dose of 500mg of Dalbavancin (study drug) through one of the catheters in your arm over 30 minutes. Blood samples will be taken to measure the levels of the study drug in your blood at the end of infusion, 4 and 12 hours after the start of infusion. You will also be given a physical examination including vital signs (heart rate, temperature, and blood pressure).

On Days 11, 15, 22 and 29, blood samples will be taken at approximately the same time that the study drug was started on Day 8. Blood will be drawn and urine collected on days 11 and 22 for laboratory testing. You will also be given a physical examination including vital signs (heart rate, temperature, and blood pressure) on day 22.

On study day 60, you will return to the clinical research center for a final outpatient visit. A blood sample will be taken at approximately the same time that the study drug was started on Day 8. You will have a complete physical exam performed including vital signs. Blood and urine samples will be taken for laboratory testing. At this visit you will be scheduled for your final Audiology Assessment (hearing test).

BLOOD SAMPLING

Blood samples may be drawn by individual needle-sticks or from an indwelling catheter directly from a vein in your arm. If the use of the catheter is not possible, the location of the needle puncture will be varied to lessen discomfort.

There will be at least 16 blood draws during the course of this study. The total volume of blood drawn will be about 215 mL (less than ½ pint). Additional blood samples may be drawn during the study if the study doctor considers it necessary for monitoring your health.

RISKS AND DISCOMFORTS

Dalbavancin has been well tolerated in healthy subjects administered up to 1120 mg dalbavancin as a single IV dose. Possible side effects are similar to those associated with taking currently available antibiotics that work in a similar manner as dalbavancin. Possible side effects may include diarrhea, dizziness, skin itchiness, abdominal pain, heartburn, headache, low grade fever, liver damage, and kidney damage. Side effects associated with the administration of the drug include pain, redness or discomfort at

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the infusion site. In exceptional cases, hearing impairment was observed with other drugs in this class that work in a similar manner. The risks to the elderly and to individuals with liver impairment may vary. In addition, it is possible that if you have liver disease that your condition may worsen.

If you have any injury, bad effect, or any other unusual health experience during this study, it is important that you tell the study doctor or the study staff immediately.

You may experience pain or redness at the infusion site during drug administration.

Unforeseen Risks/New Risks: Since the study drug is experimental, there may be risks that are unknown when the study drug is taken alone or in combination with other drugs. Serious, and in rare instances fatal, allergic reactions can occur with any medication. To date, there have been no such serious allergic reactions in patients exposed to dalbavancin. **You should notify the study doctor immediately if you experience allergy symptoms such as rash, hives, or itching. Untreated allergic symptoms can lead to a medical emergency.**

You will be informed verbally and in writing of any new information, findings or changes to the way the research will be performed that might influence your willingness to continue your participation in this study.

Blood drawing: Local pain, bruising, bleeding, blood clot formation, and in rare instances an infection might occur at the site of the needle stick where blood is drawn and at the site where the catheter is placed. There is also the possibility of dizziness or fainting while your blood is being drawn. Precautions will be taken to avoid these difficulties.

Additional risks: The electrocardiogram (ECG) procedure may cause minimal discomforts during the attachment and removal of the ECG leads to and from the skin.

Pregnancy/Fetal Risks: The effects of the study medication to the pregnant women, the embryo, the human fetus and the nursing child are not known and may be harmful. Birth defects, including physical deformities, mental retardation, and other problems, as well as premature birth are known risks of some drugs. Women who are pregnant or nursing may not take part in this study. Dalbavancin has not been studied in pregnant women.

If you suspect you are pregnant at any time during the study, you must notify the study doctor immediately. If you do become pregnant during your participation in this study, you will be discontinued from the study and all costs for care related to your pregnancy, childbirth, and post-partum/newborn care will be your responsibility.

The effects of the study medication on sperm are not known and may be harmful. You should not father a child during your participation in this study.

Restrictions: Consumption of alcoholic beverages within 48 hours of receiving study medication and until the end of the confinement is not permitted. Use of any prescription or over the counter medication or changes to your medication regimen is not permitted with the approval of the study doctor.

BENEFITS OF THE STUDY

This study is not designed to benefit you directly. Future patients may benefit from the overall conclusions drawn from the results of the study. Information obtained from this study may also benefit the sponsor of the study.

ALTERNATE TREATMENT

This study is not designed to provide treatment. You have the alternative of not participating in this study.

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COSTS AND REIMBURSEMENT

Study drug will be supplied free of charge. You will not be responsible for any of the costs of the tests and evaluations required by this protocol that go beyond what you would normally receive as part of the routine treatment of your condition.

You will be paid for taking part in this study as outlined below. This is to compensate you for your time and travel. Each portion of the study has a monetary value assigned to it, which accumulates as you participate in the study. You will be paid within 7 days of the completion of your participation in this study. No additional financial compensation will be provided.

Schedule of Payments

Visit	Amount
Screening	No Compensation
Screening audiology test visit	\$ 50.00
Day -1 (check-in/admittance)	\$ 50.00
Day 1	\$ 150.00
Day 2 (discharge from clinical research center)	\$ 50.00
Day 8 (extended visit)	\$ 100.00
Days 4, 11, 15, 22, 29, 60	\$ 45.00 each visit
Day 60 audiology test visit	\$ 50.00

If, at the completion of the study, you have been on time and participated in all clinic visits, study unit confinements, and procedures, you will receive an additional \$80.00. Thus, the total compensation for complete participation in this study will be \$800.00. If your participation in this study is terminated by the study doctor in the interests of your safety, you will still receive the extra \$80.00 in addition to compensation for the visits that you have completed. If you choose to withdraw from the study, you will receive a prorated amount based on the procedures and visits that you have **completed** as outlined above.

In agreeing to participate in this study, you will be acting as an independent contractor, not as an employee of Orlando Clinical Research Center. Because payments made to you for participating in this study may be reported to the IRS as income, you are required to provide your social security number. No deductions for any state or federal withholding or any other similar taxes will be made. It is the responsibility of the participant to report this compensation on state and federal tax returns and for the payment of any taxes that are due on this compensation.

RESEARCH-RELATED INJURIES

If you have any adverse reaction (side effect) to the study medicine during the course of the study, you should immediately contact Dr. Marbury or study personnel at (407) 240-7878, day or night.

If you become injured during this study and your injury is a direct result of the study drug or the administration of the study drug according to the study directions, medical treatment will be available to you. The costs of treatment will be paid by the Sponsor to the extent it is not covered by your health insurance. No further compensation for research related injury is available.

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Further information regarding medical treatment for research-related injuries can be obtained from the study doctor or other authorized personnel. You must notify the study doctor immediately of any research-related injury. **By signing this form you have not waived any of your legal rights.**

PARTICIPATION INFORMATION

I understand that I am free to withdraw from this study at any time, and I agree to inform the physician immediately if I intend to withdraw. It is understood that my decision to participate in this study or to withdraw from this study will not influence the availability of my future medical care and will involve no penalty or loss of benefits to which I am otherwise entitled. I may withdraw from this study at any time.

I agree that the physician in charge of the study can remove me from this study without my consent for any reason, including, but not limited to:

- a. His/her judgment that any condition or circumstance may jeopardize my welfare or the integrity of the study.
- b. My failure to follow the instructions of the investigator(s).
- c. If the study is stopped by the sponsor and/or doctors participating in the study prior to completion.

The sponsor, IRB or the FDA may stop the study at any time.

Any time your participation is terminated or if you withdraw voluntarily from the study, you will be asked questions about your participation in the study and to complete final laboratory tests and study procedures possibly including the audiology evaluation. It is important for your health and safety to have these final procedures completed.

CONFIDENTIALITY

You should understand that all information collected in this study will be kept strictly confidential, except as required by law. In addition, information from this study, medical records which identify you and the consent form signed by you, may be submitted to, inspected and or copied by; the study sponsor, the Sponsor's representatives (such as contract research organizations), Orlando Clinical Research Center, the FDA, governmental agencies in other countries where the study drug may be considered for approval, and the Independent Investigational Review Board, Inc. Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research study may be presented at meetings or in publications, however, your identity will not be disclosed in these presentations.

USE AND DISCLOSURE OF MEDICAL INFORMATION

As part of this study, the study Doctor, will collect personal health information (the "study information"), including, but not limited to personal information that you provide including your age, sex, medical/surgical history, past and current medications, etc., the results of procedures and tests you undergo during the study or had before the study, information about your response to treatments you receive under the study, and other medical information relating to your participation in this study, under federal law, cannot be used or disclosed for research purposes unless you sign this authorization. *You may not participate in the research study unless you sign this authorization.* **If you sign this informed consent form, you will be agreeing to the disclosures described below:**

Medical information relating to your participation in the study may be disclosed by the investigator or other research study staff to the study sponsor, Versicor and its employees, agents and/or contractors. Versicor, in turn, will collate and interpret the study information and report it to the U.S. Food and Drug Administration ("FDA") for evaluation by the FDA for the purpose of determining if the FDA will grant regulatory approval for the drug dalbavancin. The investigator or other research study staff may also disclose study information to the Independent Investigational Review Board, Inc., an Institutional Review Board ("IRB") that oversees the conduct of the research study for the purpose of protecting the rights and welfare of subjects enrolled in the research study.

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Once the research facility discloses information in your study records or medical records to the study sponsor or its consultants, the information will no longer be protected by federal law.

This authorization will expire at the completion of the entire research study. You have the right to revoke this authorization at any time, provided that the revocation is in writing. However, if you exercise your right to revoke this authorization, you will be discontinued from participation in the research study.

If you drop out of the study, you do not have to revoke your authorization to use and disclose your medical information. However, if you drop out of the study and do decide to revoke your authorization to use and disclose your medical information, the information that has already been collected in your study record may continue to be used and disclosed as described above, however, no new information will be obtained.

Volunteer Initials

PERSONS TO CONTACT

You have the right to ask any questions concerning the potential and/or unknown hazards of this study at any time. If you have any questions concerning your participation in this study, or if at any time you feel you have experienced a research-related injury or a reaction to the study medication, contact Dr. Marbury or his research staff at [REDACTED] 24-hours a day.

If you have any questions about your rights as a research subject, please contact Kim Lerner, Chairman of the Independent Investigational Review Board, Inc. toll free at (866) 475-8666 during regular working hours. The Independent Investigational Review Board is a committee established for the purpose of protecting the rights of volunteers in a research study.

Do not sign this form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

CONSENT

You have read and understood the information that has been stated above and have received satisfactory answers to all of the questions that you have asked and you willingly sign this consent form. You will receive a copy of the signed informed consent and you hereby consent to be a participant in this study.

SIGNATURES

I have read in a language that I understand well, the above information. The content and meaning of this information has been explained to me. I hereby voluntarily consent and offer to take part in this study.

Print Subject Name	Subject Signature	Date/Time
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The information contained in this document was fully and carefully explained to the study participant. Furthermore, the study participant has been given the opportunity to ask any questions regarding the nature, risks, and benefits of his/her participation in this research study.

Printed Name of Person conducting the Informed Consent discussion	Signature of Person conducting the Informed Consent discussion	Date/Time
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