

**A Phase I Open Label Study to Assess the Effect of Intravenous Dalbavancin on
the Intestinal Flora of Healthy Subjects**

Informed Consent Form For:

**A Phase I Open Label Study to Assess the Effect of Intravenous
Dalbavancin on the Intestinal Flora of Healthy Subjects**

Protocol: VER001-15

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

Investigator:
Name
Affiliation
Street Address
City, State
Telephone Number (24 hours)
Beeper number

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Invitation to Participate: You are being asked to participate in a clinical research study being conducted by Dr. _____ and his/her designated study staff to test the effect of an experimental antibiotic dalbavancin on the bacteria in your intestines. This research is funded by Vicuron Pharmaceuticals, Inc. (the sponsor company). The investigator and/or members of his/her study staff enrolling you into the study will be financially reimbursed for conducting the study. In order for you to decide whether or not you agree to be part of this research study, you should understand enough about its risks and benefits to make an informed judgment. This process is known as informed consent.

This informed consent form gives you detailed information about the research study, which the investigator or a member of his/her study staff will discuss with you. This discussion should go over all parts of this research study: its purposes, the procedures that will be performed, any risks of the procedures, possible benefits, and possible alternative treatments. Once you understand the study and all your questions have been answered, if you still wish to participate, you, along with the investigator or a member of his/her study staff and a witness, will be asked to sign this informed consent and you will receive a copy of it to keep as a record.

You understand that although the study will be under the direct supervision of this investigator, other professionals (doctors, nurses, etc.) who work with the investigator may be designated to assist or act for him/her.

Purpose: 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. Vicuron Pharmaceuticals, Inc. is developing a new antibiotic, known as dalbavancin, which may be effective against a variety of bacterial infections that affect the skin and bloodstream and are difficult to treat. The purpose of this study is to determine the effect of dalbavancin on bacteria that normally live in the intestine of healthy volunteers.

Duration: Your participation in this study will last for a maximum of 60 days.

Selection of Subjects: This research study will be conducted at approximately 1 center and will involve approximately twelve (12) subjects, who are at least 18 years old. All twelve (12) subjects will participate from _____ (institution name).

The investigator and/or study staff will evaluate your medical condition and history to determine whether you are eligible to participate in this study. In addition, you may **NOT** participate in this study if any of the following apply to you:

1. Participation in any investigational drug or device study within the previous 30 months;

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2. Known allergy to any glycopeptide antibiotic (for example, vancomycin);
3. Current substance abuse (including drugs of any kind and alcohol intake that exceeds 24 oz. of beer or the equivalent per day);
4. If you are a female: Pregnant or nursing, or unwilling to practice an effective method of birth control during the study and for at least 6 weeks after your last dose of study drug;
5. Blood or blood product donation within 60 days of the start of the study;
6. No means of contacting or visiting the investigator and/or study staff as required by the study or in the event of an emergency.

Procedures: You will receive a single 1000 mg IV (in your vein) dose of dalbavancin.

Before entering this study or undergoing any tests for the study, you will be asked to sign this informed consent form, indicating your willingness to participate in this study. In order to be eligible to participate in this study, you must meet certain criteria that will be evaluated and determined by the investigator and/or study staff. You must agree to attend all scheduled visits and follow instructions given to you by the study staff. If you agree to participate in this study, the following events will occur:

Screening: Before receiving study drug, you will be asked about your medical/surgical history in the previous 3 months and any medications you have taken in the previous 3 months and/or are currently taking. You will also be given a physical examination including 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.

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 morning of study drug administration. 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. You will be asked to provide a fecal sample within two days prior to receiving the study medication.

On Study (Admitted to the Clinical Research Center): On Day 1 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

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samples will be drawn and vital signs will be taken.

You will receive a single dose of 1000 mg 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, and at 6 hours after the start of infusion. Your blood pressure, pulse, respiration, and temperature will be taken at the end of the infusion and 6 hours after the start of the infusion. You will go home after approximately 6 hours of observation and after all procedures have been completed.

On Study: You will return to the Clinical Research Center on days 2, 3, 5, 7, 14, 21, 28, 35, 42, and 60. At each visit, blood samples will be taken at approximately the same time that the study drug was started on Day 1. You will be asked to collect the first fecal sample passed for the day on Days 2 and 5. If none is passed on the given day, the next specimen passed will be collected. You will be asked to collect a fecal sample within a week of study Days 14. You will be asked to collect a fecal sample within a week of either study Day 28 or 35 and within a week prior to study Day 60. All fecal samples must be returned to the clinic within 4 hours. You will also be given a physical examination including vital signs (heart rate, temperature, and blood pressure) on days 7 and 60. Blood will be drawn on days 7 and 60 for laboratory testing.

On Day 1 and for the duration of the study, you will be monitored closely for possible side effects. 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.

You have the right to either refuse to participate and/or stop your participation in this study at any time and for any reason without penalty or loss of benefits to which you would otherwise be entitled.

Benefits: No direct benefit can be guaranteed to you by participation in this clinical study. While you may not receive direct benefits, your participation in this study may benefit future patients by providing important information about this potentially useful antibiotic drug.

Risks: 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 marketed antibiotics that are in the same class of drugs as dalbavancin. Possible side effects may include diarrhea, abdominal pain, heartburn, headache, and low grade fever (37.1-37.5°C).

Risks associated with drawing blood from your arm include pain, bruising, swelling, lightheadedness, and on rare occasion, infection and nerve damage (some numbness

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and tingling.

If you become pregnant during the course of this study, you should notify the investigator as soon as possible, since the risks to pregnant women, the embryo, the fetus and nursing children are unknown.

There also may be risks and discomforts that are not yet known.

New Findings: You will be told in a timely manner of any significant new information regarding the safety and/or effectiveness of dalbavancin that may affect your willingness to stay in this study.

Costs: You will not incur any charges for study drug or study related procedures.

Compensation: You will not receive any payment for participation in this study.

Alternatives: This study is not designed to provide treatment. The only alternative to participation is to not participate in this study.

Confidentiality: You should understand that all information collected in this study will be kept strictly confidential, except as required by law. All personal health information collected in this research study (the "study information"), including, but not limited to medical/surgical history, past and current medications, vital signs, physical examination and laboratory results, other assessments and samples may be disclosed by the investigator or other research study staff to the study sponsor, Vicuron and its employees, agents and/or contractors. Vicuron, in turn, will collate and interpret the study information and report it to the U.S. Food and Drug Administration ("FDA") and/or other appropriate governmental agencies, who will use this information for the purposes of determining whether or not to grant regulatory approval for the drug dalbavancin. The investigator or other research study staff may also disclose study information to the Institutional Review Board ("IRB")/Ethics Committee ("EC") that oversees the conduct of the research study for the purpose of protecting the rights and welfare of subjects enrolled in the research study. Your medical records and information will be kept confidential within the limits of the law. If any publication results from this research your identity will not be revealed.

Your signature on this informed consent form also serves as the authorization for the disclosure of the study information as outlined above. This authorization will expire at the end of the 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. Any study information disclosed before the authorization is revoked cannot be retracted or retrieved and any actions taken in reliance on this information will not be affected. Absolute confidentiality of the study information cannot be guaranteed. Disclosed study information may be subject to further disclosure by the recipients of the

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study information and therefore, may no longer be protected under federal privacy regulations.

Withdrawal: Your participation in this study is completely voluntary and you may either refuse to participate or withdraw at any time without penalty, without affecting your present or future care by the hospital, or without loss of benefits to which you would otherwise be entitled. Also understand that should the investigator and/or study staff, the sponsor (Vicuron Inc.), the Institutional Review Board (IRB)/Ethics Committee (EC), or the US Food and Drug Administration (FDA) find it necessary and/or in your best interests, they may withdraw you from this study or stop the entire study without your consent.

In the event that you stop participating in the study for any reason, you will be asked to return to the research center to undergo the final evaluations. It is important for your health and safety to have these final procedures completed.

Injury: If you participate in this study you will be exposed to certain risks of physical injury, in addition to those connected with standard forms of therapy (see "Risks" section). In addition, it is possible that in the course of this study, new side effects of dalbavancin that result in physical injury may be discovered. Medical therapy will be arranged by _____ (institution name) if you have been injured as a direct result of participation in this research study.

Vicuron Inc. (sponsor) will pay for medical care to treat any physical injury incurred as a direct result of the study drug or study procedures. You agree to cooperate in obtaining any proceeds from insurance or other third party coverage that may be available to you for such medical care. No financial payments or other forms of compensation (such as lost wages or discomfort) or medical treatment beyond that which is offered above will be available; however, your legal rights are not waived by signing this form.

Subject Rights and Research-Related Injury: If you need further information regarding your rights as a research subject, you may contact _____ at (xxx) xxx-xxxx. This individual is an impartial person who is not involved in the conduct of the study. If you believe you have been injured due to study procedures or if you have any questions about the research, or your rights as a research subject, contact Dr. _____ by calling (xxx) xxx-xxxx. You should take this opportunity to ask questions and have them answered to your satisfaction.

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SIGNATURE OF SUBJECT or LEGALLY ACCEPTABLE REPRESENTATIVE

You, ([] subject, [] legal guardian, [] surrogate or [] caregiver) understand this informed consent form after having read it and having it explained to you in your primary language (or interpreted accordingly), and have been given enough time to decide whether to participate. You freely agree to participate (or agree to the subject's participation, if you are a legally acceptable representative) in this research study. Upon signing below, you will receive a copy of the consent form.

Printed Name of Subject

Date & Time

Signature of Subject

Printed Name of Legally Acceptable Representative, *if applicable*

Date & Time, *if applicable*

Signature of Legally Acceptable Representative, *if applicable*

Relationship to Subject, *if applicable*

SIGNATURE OF READER/TRANSLATOR IF THE SUBJECT / LEGALLY ACCEPTABLE REPRESENTATIVE DOES NOT READ ENGLISH WELL

The person, who has signed above, _____, does not read English well. You, the reader / translator, read English well and are fluent in (name of the language) _____, a language the subject or legally acceptable representative understands well. You have translated for the subject or legally acceptable representative the entire content of this informed consent form. To the best of your knowledge, the subject or legally acceptable representative understands the contents of this informed consent form and has had an opportunity to ask questions regarding the informed consent form and the study, and that these questions have been answered to the complete satisfaction of the subject or legally acceptable representative.

Printed Name of Reader / Translator, *if applicable*

Date & Time, *if applicable*

Signature of Reader / Translator, *if applicable*

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SIGNATURE OF WITNESS

You, the witness, confirms, to the best of your knowledge, that the subject or legally acceptable representative understands the contents of this informed consent form and has had an opportunity to ask questions regarding the informed consent form and the study, and that these questions have been answered to the complete satisfaction of the subject or legally acceptable representative.

Printed Name of Witness

Date & Time

Signature of Witness

***SIGNATURE OF PERSON CONDUCTING THE INFORMED CONSENT
(Investigator or Designated Study Staff Representative)***

To the best of my knowledge the subject, (or legally acceptable representative) _____, has assimilated the entire content of the above consent form, and understands the study and its risks well. The subject's questions and/or those of his/her legally acceptable representative have been accurately answered to his/her/their complete satisfaction.

Printed Name of Person Conducting Informed Consent

Date & Time

Signature of Person Conducting Informed Consent