

APPENDIX A.1.2
SAMPLE INFORMED CONSENT FORM

Informed Consent For Phase II Pilot, Randomized, Open-Label, Multi-center Study to
Evaluate the Safety and Efficacy of Dalbavancin Versus Investigator/Physician
Designated Comparator in Skin and Soft Tissue Infection

Invitation to Participate: You are being asked to participate in a clinical research study being conducted by Dr. _____. This study is designed to test the safety and efficacy of the experimental antibiotic dalbavancin on skin and soft tissue infections. In order to decide whether or not you should 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 consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: 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 will be asked to sign this informed consent and you will receive a copy of it to keep as a record. You understand that while the study will be under the supervision of this doctor, other professionals who work with him/her may be designated to assist or act for him/her.

Purpose: Versicor, Inc. is developing a new antibiotic, known as dalbavancin (also known as VER001), which has been shown to be effective against a variety of bacterial infections that are difficult to treat. The purpose of this study is to evaluate the potential effectiveness, safety, and tolerance of dalbavancin in the treatment of adults with skin and skin structure infections.

Duration: Your participation in this study will last for approximately 24-37 days.

Selection of Subjects: This is a multi-institutional study, which will involve a total of sixty patients. You are eligible to participate in this research study because you have been diagnosed with a bacterial skin and/or skin structure infection. There may be reasons why you cannot participate which will be discussed with you by the investigator or his/her staff.

Procedures:

The study doctor or staff will ask you about your medical history and examine you. You will be assigned by chance (like picking a name from a hat) to one of three groups.

Group 1 will receive a one time dose of 1100 mg dalbavancin intravenously (IV).

Group 2 will receive a 1000 mg dose of dalbavancin IV followed by a 500 mg dose IV 8 days later.

Group 3 will receive standard IV antibiotic treatment as determined by your medical doctor prior to randomization.

You have a 2 in 3 chance of receiving the active study drug. In an emergency, information about what drug you are on can be obtained quickly.

The study includes 6 visits each lasting approximately 45 minutes to 3 hours. Visits will take place at; time of screening (prior to receiving study drug), on Day 1, Day 3, Day 8, at the end of IV study therapy and at 14 days post study therapy. If you are in the hospital, the study doctor will visit you and procedures will be performed at the bedside. If you are not hospitalized or discharged prior to study completion you will be requested to visit the study doctor in his/her office. The following procedures will be performed during your study visits:

- Obtain blood for testing of blood counts, chemistries, and dalbavancin levels (<1 tablespoon per visit which will be obtained with routine blood work whenever possible)
- Obtain urine sample
- Physical examination
- Vital signs (temperature, blood pressure, pulse, and respiratory rate)
- Examine you, culture your wound, and may photograph your wound

In addition to the above procedures, the screening visit will also include:

- Medical history
- Electrocardiogram (EKG ;a tracing of your heart rhythm)
- Hearing test
- Pregnancy test for women of childbearing potential

Benefits: There can be no guarantee of benefit with any antibiotic. If the drug works you may receive some benefit. If it does not work, you personally will not receive any clinical benefit from your participation in this study. While you may not receive direct benefits, your participation in this study may benefit future patients with skin and soft tissue infections.

Risks: Dalbavancin has been well-tolerated in healthy subjects administered up to 1120 mg dalbavancin as a single intravenous dose. Possible side effects associated with administration of marketed antibiotics that are in the same class of drugs as dalbavancin (such as vancomycin) may include diarrhea, abdominal pain, heartburn, liver damage, kidney damage, and, in exceptional cases, hearing impairment.

In a study conducted at UMDNJ, in which to date 33 healthy volunteers have received dalbavancin; there were no signs of any of the above-mentioned side effects. In several of the volunteers, a slight increase in body temperature of about 1-2 degrees Fahrenheit was observed.

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

It is not known how the study drug(s) may affect an unborn baby. If you are a woman of childbearing potential, you must agree to remain abstinent (no sexual intercourse) or use a barrier method of birth control (diaphragm with spermicidal gel or condoms with contraceptive foam) for the duration of the study and continue to use birth control until at least 30 days after you have stopped taking the study medication. Oral contraceptives are not to be used as the sole method of birth control. Your study doctor can discuss methods of birth control with you and refer you elsewhere for more information, if needed.

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: This research is funded by Versicor, Inc. You will not incur any charges for study drug or study related procedures. Charges that are part of your routine care, and not required by the protocol, will remain your responsibility or that of your insurance company.

Compensation: You will not receive any payment for participation in this study. However, subjects that are not hospitalized or discharged from the hospital prior to Day 14 will be reimbursed \$25 per study visit for time and travel expenses to return for your study visit, up to a maximum of \$100.

Alternatives: Standard antibiotic therapy is available if you choose not to participate in this study. Your medical doctor would determine alternative therapy. Consult your physician for more information regarding alternative treatments.

Confidentiality: You should understand that all information collected in this study will be kept strictly confidential, except as required by law. Further understand that representatives of the Institutional Review Board (IRB), the sponsoring company Versicor, Inc., agencies designated to act on behalf of the Sponsor, the Food and Drug Administration (FDA) and other appropriate governmental agencies may review the data collected from this 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.

Withdrawal: Your participation in this study is completely voluntary and you may withdraw at any time without penalty or prejudicing your present or future care. Also understand that should your doctor(s) or the sponsor (Versicor, Inc.) find it necessary, and/or in your best interests, they may withdraw you from this study. If you withdraw from this study, you will be asked to return to your doctor in order to complete final study procedures.

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 adverse effects of dalbavancin that result in physical injury may be discovered. Medical therapy will be arranged by your study doctor/staff for any physical injuries sustained as a direct consequence of participation in this research.

Versicor, Inc. will pay for medical care to treat any physical injury incurred as a direct result of the study drug or study procedures. 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: If you need further information regarding your rights as a research subject, you may contact the Institutional Review Board at xxx-xxx-xxxx. If you believe you have sustained an injury due to study procedures or if you have any questions about the research, contact Dr. _____ at xxx xxx-xxxx. You should take this opportunity to ask questions and have them answered to your satisfaction.

Conclusion: You, ([] patient, [] legal guardian, or [] caregiver) understand this consent form after having read it and having it explained. You freely agree to participate in this research study. You will receive a copy of the consent form.

Signature of Patient/Person giving consent

Date

Relationship to patient: _____

Signature of Witness

Date

Signature of Investigator

Date