

## INFORMATION AND CONSENT FORM

**Study Title:**

**Study #:**

**Sponsor:**

**Study Doctor:**

**Telephone Number:**

**After Office Hours:**

You have been asked to participate in a research study of a new investigational antibiotic called dalbavancin because your doctor has determined that you have an infection of your skin and nearby tissues that requires antibiotics.

The following consent form describes the study in order to help you decide if you want to participate. It will tell you what will happen during this research study, what you will have to do and what the risks, benefits and alternatives are of participating.

This consent form may contain words that you do not understand. Your study doctor will answer any questions you may have about this form and about the study. Please read this information carefully and do not hesitate to ask any questions about the study information provided below. You can discuss your participation with anyone you choose in order to better understand this research study and your options.

Do not sign this consent form unless the study doctor or study staff has answered all of your questions and you have decided that you want to be a part of this research study.

Being in this study does not replace your regular medical care.

### WHAT IS THIS RESEARCH STUDY ABOUT?

Dalbavancin is an investigational antibiotic drug being developed by Durata Therapeutics, Inc., the sponsor of this study, for the potential treatment of skin and nearby tissue infections. In the United States an investigational drug is a drug that is being tested under the regulations of the U.S. Food and Drug Administration (FDA), but has not been approved for sale or general public use.

Dalbavancin belongs to a class of antibiotics called glycopeptides. It belongs to the same class of drugs as vancomycin and teicoplanin, two commonly used drugs, and one of the few treatments available to treat infections caused by a type of bacteria resistant to certain antibiotics, known as methicillin-resistant *Staphylococcus aureus* (MRSA). Dalbavancin is a new antibiotic that may be at least as effective as currently available treatments and may allow once-a-week dosing. However, there is no guarantee that dalbavancin will work in this way.

## **PURPOSE AND OVERVIEW OF THE STUDY**

As of November 12, 2010, dalbavancin has been given by injection into a vein (administered intravenously, or IV) to 1292 people who participated in 14 clinical studies. It is expected that approximately 556 participants will be enrolled in this study worldwide.

In this study, the safety, tolerability and efficacy of dalbavancin is being compared to intravenous (IV) vancomycin, which is approved by the FDA for the treatment of bacterial skin infections. You will be assigned by chance to receive either IV dalbavancin or placebo (a substance that looks like the study drug that contains no active ingredients) on Day 1 and Day 8 to be infused over the course of 30 minutes and IV vancomycin (1000 mg or 15 mg/kg) or placebo every 12 hours for 10-14 days to be infused over the course of 2 hours. The amount of dalbavancin you might receive may vary. The study doctor can tell you more about this. You will have an equal ("50/50") chance of being assigned either drug, like flipping a coin. Everyone will receive active study drug and placebo during some part of the study.

Unless otherwise indicated, whenever this consent form refers to "study drug", it means dalbavancin, vancomycin, linezolid or placebo.

If after at least 6 doses of study drug, your study doctor thinks your infection is responding, you may be switched from the every 12 hours IV dosing to an oral drug called linezolid (every 12 hours) if you are assigned to the vancomycin group, or matching oral placebo if you are assigned to the dalbavancin group. Linezolid is also approved by the FDA in the United States for the treatment of bacterial skin infections.

This study is blinded, which means neither you nor the study doctor evaluating your infection will know which study drug you are taking. In the event of an emergency, the study doctor can find out which study drug you are receiving.

In addition to the study drugs, the study doctor may decide to give you additional antibiotics, such as aztreonam and/or metronidazole, at the same time to try and help your infection.

## **HOW DO I KNOW IF I CAN BE IN THIS RESEARCH STUDY?**

If you choose to participate in this study, you will sign this information and consent form, then you will be examined by the study doctor and several tests will be performed. These procedures will be done before you are given the first dose of study drug, so that the study doctor can determine if you qualify for the study. If you do not qualify for this research study, the study doctor will tell you the reason(s). If you do qualify for the study, you will begin to receive study drug.

## **HOW LONG WILL I BE IN THIS RESEARCH STUDY?**

If you decide to participate in this research study, your participation will last anywhere from 60 to 88 days. You will be treated with study drug generally for no more than 14 days. You will see the study doctor daily while you are receiving IV study drug. You will also be asked to attend a total of 9 study visits. The study visits are very important to see if the study drug is helping your infection and is safe. If you participate in this study, you must be willing to come to all the study

visits. The study staff will tell you when to come in for your study visits and about how long your visits will last.

#### **WHAT WILL HAPPEN DURING THIS STUDY?**

At first, you will be given this Information and Consent Form and you will be asked to sign if you agree to participate in this study. Nothing further will happen unless you consent by signing the information and consent form. If you agree to participate, in order to determine if you are eligible for the study, you will have the following tests and procedures done during your baseline visit:

- You will be asked to give personal information, such as date of birth, race, gender, etc.
- You will be asked about your medical history (including any history of recreational drug, alcohol and tobacco use);
- You will be asked about all the medicines you are currently taking and about any other drug treatments (such as topical solutions or bedside wound care), as well as any medicines you have taken within the last 30 days;
- You will have a complete physical exam and your height and weight will be measured;
- Your vital signs (blood pressure, heart rate, breathing rate, and temperature) will be recorded;
- You will have blood drawn (about 1 tablespoon) for routine lab tests. You may need to fast (not have anything to eat or drink but water) for 8 hours before the study visit for this blood draw;
- You will also have blood drawn for what is called a blood culture test to determine if you have an infection in your blood. Two blood culture specimens will be drawn from different sites on your body (about a 1.3 tablespoons each for a total volume of 2.6 tablespoons) approximately 5 minutes apart. Per study requirements, if this test is positive for a Gram-positive infection at your baseline visit, it should be repeated a second time, 48 to 72 hours after your first study drug dose, or as needed. If the results are again positive for the same infection, the test should be repeated a third time, 48 hours after the last test was performed. If results are positive for the same infection on the third test, you will be withdrawn from study drug and treated per standard of care. This test should also be repeated at the End of Treatment visit if the test was positive at the baseline visit. The maximum number of times you may have blood culture tests performed is four times. The total maximum amount of blood that could be drawn for all tests combined is approximately 11 tablespoons.
- Some of your blood from this visit and from the Day 3 visit will be stored and may be used for future safety or other testing. The purpose of the additional blood tests is to learn more about the study drug dalbavancin and about acute bacterial skin and skin structure infections. The results of the tests that may be performed on your samples will not affect your participation in this study. Your stored samples for this study will be maintained at Eurofins Global Central Laboratory, Inc., [REDACTED] Park Meadow Dr., Suite 110 Chantilly, VA [REDACTED], USA for a minimum of 7 years after study completion, and then destroyed. Stored blood will not be used for genetic testing. Samples will be identified by a barcode number. Initials will not be utilized as a subject identifier. Other serum samples will be stored through the completion of the study.

- If you are a female capable of getting pregnant, your blood will be used for a pregnancy test or a urine sample for pregnancy testing may be collected. You will be told if the results are positive. If you are pregnant, you cannot be in this study;
- A blood hormone test will be performed for women who are post-menopausal and less than 50 years of age or 50 years of age or older who have been post-menopausal for less than 2 years;
- You will have an electrocardiogram ("ECG"). An ECG is a test to record the electrical activity of your heart. For this test, you lie down and probes are placed on your chest and wrists and ankles. There are no needles. The test generally takes about 5 minutes.
- Your infection will be evaluated by testing lab samples from the area of your skin that is infected as well as by taking measurements and photographs;
- You will be given a questionnaire that asks you about any pain you might be feeling;
- Your study doctor will check how you are feeling;
- Your study doctor will tell you if any of your laboratory tests reveal any medical problems that you do not already know about.

Based on these tests, the study doctor will determine if you can be in this study. If you can, you will begin treatment by being given study drug by IV infusion (by vein).

### **Dosing Period**

#### **DAY 1**

- At this visit, you will be given your first dose of study drug by IV infusion;
- Infusion will last approximately 30 minutes and two hours;
- Approximately 12 hours later, you will receive another two hour infusion;
- Your temperature will be checked every 6 hours;
- Your study doctor will check how you are feeling.

#### **DAY 2**

- At this visit, you will be given two doses of study drug by IV infusion approximately 12 hours apart;
- You will have your vital signs measured and the site of your skin infection will be checked, measured and photographed;
- Your temperature will be checked every 6 hours;
- Your study doctor will check how you are feeling.

#### **DAY 3**

- A brief physical exam will be performed during this visit to check for any changes since your first visit with the study doctor;
- You will have your vital signs measured;
- The site of your skin infection will be checked, measured and photographed;
- Samples of the infection on your skin may be collected for lab testing;

- You will have blood drawn (about 1 tablespoon) for routine lab tests. You may need to fast (not have anything to eat or drink but water) for 8 hours before the study visit for this blood draw;
- Some of your blood may be stored and used for future safety or other testing. Stored blood will not be used for genetic testing. Samples will be identified by a barcode number. Initials will not be utilized as a subject identifier. Banked serum samples will be stored for at least 7 years. Other serum samples will be stored through the completion of the study.
- You will be given a questionnaire that asks you about any pain you might be feeling;
- Your temperature will be checked every 6 hours;
- Your study doctor will ask you how you are feeling;
- You will be asked about all the medicines you are currently taking including any non-drug treatment (such as topical solutions or bedside wound care);
- At this visit, you will be given two doses of study drug by IV infusion approximately 12 hours apart.

#### **DAY 4**

- You will have your vital signs measured;
- The site of your skin infection will be checked, measured and photographed;
- At this visit, you will be given two doses of study drug by IV infusion or a pill by mouth approximately 12 hours apart as determined by your doctor;
- Your study doctor will check how you are feeling.

#### **DAY 5 through DAY 7**

- On these days, you will be given two doses of study drug by IV infusion or a pill by mouth approximately 12 hours apart as determined by your study doctor.

#### **DAY 8**

- You will have your vital signs measured;
- The site of your skin infection will be checked, measured and photographed;
- Samples of the infection on your skin may be collected for lab testing;
- You will be asked about all the medicines you are currently taking including any non-drug treatment (such as topical solutions or bedside wound care);
- Your study doctor will ask you how you are feeling;
- At this visit, you will be given study drug by IV infusion for 30 minutes, and another infusion for two hours or a pill by mouth as determined by your study doctor;
- Approximately 12 hours later, you will receive another two hour infusion or a pill by mouth as determined by your study doctor.

### **DAY 9 through DAY 14**

- On days 9 and 10, and possibly through day 14, you will be given two doses of study drug by IV infusion or a pill by mouth approximately 12 hours apart as determined by your study doctor.

### **End of Treatment**

Day 14 or 15 (or within 3 days after stopping study drug early)

- A brief physical exam will be performed during this visit to check for any changes since your first visit with the study doctor;
- You will have your vital signs measured;
- You will have blood drawn (about 1 tablespoon) for routine lab tests. You may need to fast (not have anything to eat or drink but water) for 8 hours before the study visit for this blood draw;
- The site of your skin infection will be checked, measured and photographed;
- Samples of the infection on your skin may be collected for lab testing;
- You will be given a questionnaire that asks you about any pain you might be feeling;
- You will be asked about all the medicines you are currently taking including any non-drug treatment (such as topical solutions or bedside wound care);
- At this visit, you may be given study drug by IV infusion or a pill by mouth;
- Your study doctor will ask you how you are feeling.

### **Follow-Up Visits**

- You will have a follow-up study visit about 26 to 30 days after your first dose of study drug and then again around 70 days from your first dose of study drug.
- Even if you stop taking study drug early, you will still be asked to return for a follow-up visit.
- During the follow-up visits, a brief physical exam will be performed to check for any changes since your first visit with the study doctor;
- You will have your vital signs measured;
- You may have blood drawn (about a ½ tablespoon) for routine lab tests;
- If you are a female capable of getting pregnant, a urine sample for pregnancy testing will be collected. You will be told if the results are positive. If you are pregnant, you cannot continue in the study;
- The site of your skin infection will be checked, measured and photographed;
- Samples of the infection on your skin may be collected for lab testing;
- You will be asked about all the medicines you are currently taking including any non-drug treatment (such as topical solutions or bedside wound care);
- Your study doctor will ask you how you are feeling;

Your temperature will be taken every day (sometimes more than once) when you are seen for the study. If you are not in the study clinic when temperature measurements are scheduled (every 6 hours at least during the first three days), you will need to take and record these temperatures on your own with the thermometer the study staff gives you.

If you decide to participate in the study, consider if you have the time it will take for you to participate, keep appointments, and to follow the study rules. You will be asked to truthfully tell the study doctor about your complete medical history, and to report any new problems, illnesses, or changes in medication during the study. You will be expected to follow directions for taking the study drug (only you should take the study drug) and for returning the study drug to the office. You may be asked to stop taking some medicines or vitamins during the study. If you stop taking any of your regular medications to be in the study, your infections symptoms may come back or get worse. You may also be asked to keep track of the dates, times and how much medicine you took while at home and bring this information back to your study doctor's office for review.

While you are in the study, you must:

- Follow the instructions you are given.
- Come to the study center for all visits with the study doctor.
- Tell the study doctor or study staff about any changes in your health or the way you feel.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

#### **HOW WILL MY PHOTOGRAPHS BE USED FOR THIS STUDY?**

Photographs of the infected area on your body will be taken at several points during the study and will be part of your study record. In these photographs you will be identified only by a subject number and the date, but not by your name. If the infected area is on your face, the photographs will be altered to cover uninfected portions of your face so no one can recognize you. There is always a possibility, however, that someone may still recognize you from the photographs of your infection area. You do not have to let the study doctor or study staff take photos if you don't want to. However, you cannot be in the study if you do not want the study doctor or study staff to take photos. You can ask the study doctor or study staff questions about it before you decide if you want to let them take photos.

By signing this consent form, you are agreeing to have photographs taken of the infected area on your body. Photographs may be used in presentations or publications to show the infections studied and their response to treatment.

#### **WHAT ARE THE RISKS OF THE STUDY DRUGS USED IN THIS STUDY?**

Certain side effects and discomforts associated with the study may occur. As with taking any drug, there is a risk of allergic reaction. There may also be side effects and discomforts that are not yet known. Everyone will receive active study drug (either dalbavancin or vancomycin/linezolid) and placebo during some part of the study. Regardless of which study drug you are assigned to receive (vancomycin, placebo [inactive substance] or dalbavancin), your symptoms may not improve or may worsen.

#### **Risks Associated with Dalbavancin**

The most common and expected side effects and discomforts reported for all study drugs in previous studies of Dalbavancin included nausea, diarrhea and headache, which were reported less frequently in people who received dalbavancin than in people receiving the comparison

study drug. Side effects considered possibly or probably related to study drug were reported by a smaller number of dalbavancin-treated people than people treated with a comparator drug. Side effects that occurred in 1% or more of dalbavancin-treated people included the side effects listed above, as well as liver enzyme (GGT) and tissue enzyme (LDH) increases, rash, and vomiting. The majority of side effects reported in previous studies were mild or moderate in severity.

Pseudomembranous colitis, or antibiotic-associated diarrhea, is an infection of the colon and has been reported with nearly all antibiotics, including dalbavancin. In previous studies with dalbavancin, this infection was moderate in severity.

In previous late stage studies, increases or decreases in blood sugar (glucose) were more common in people treated with dalbavancin compared to participants receiving the comparison study drug.

Abnormal liver function tests (ALT, AST, bilirubin) were reported with similar frequency in participants receiving dalbavancin or comparison study drug.

Some previous study participants had to discontinue study drug due to side effects. The most common side effects resulting in participant discontinuation included rash and itching. These side effects were seen at a similar frequency in participants taking dalbavancin as participants taking the comparison study drug.

More serious reported side effects included cellulitis (redness, heat, tenderness or swelling around the infected area) and two reported instances of leukopenia (a decrease in the number of white blood cells in your blood that fight infection). Both of the participants with leukopenia recovered and did not stop taking study drug.

In summary, the most common and expected side effects reported by participants in previous studies included (percentage of the study participants receiving dalbavancin that experienced the side effect):

- diarrhea 3.0%
- nausea 2.8%
- rash 1.4%
- increased liver enzyme (GGT) 1.4%
- headache 1.2%
- vomiting 1.2%
- increased tissue enzyme (LDH) 1.2 %

Pseudomembranous colitis and antibiotic-associated diarrhea, is an infection of the colon and has been reported with nearly all antibiotics, including dalbavancin (0.3% of participants receiving dalbavancin).

In previous studies, increases (0.6%) or decreases (0.5%) in blood sugar (glucose) were more common in participants receiving dalbavancin compared to participants receiving the comparison study drug.

Some previous study participants discontinued dalbavancin due to side effects. The most common of these were rash (0.6%) and itching (0.2%).

More serious reported side effects in participants receiving dalbavancin included cellulitis (1.2%) (redness, heat, tenderness or swelling around the infected area) and two (0.1%) reported

instances of leukopenia (a decrease in the number of white blood cells in your blood that fight infection). Both of the participants with leukopenia got better and did not stop taking study drug.

### **Risks Associated with Vancomycin**

Vancomycin is an antibiotic that is used when methicillin-resistant staphylococci are suspected. Possible side effects of vancomycin include the following:

More than 10% of the participants experienced the following:

- Low blood pressure with flushing
- Rash on face and upper body
- Nausea

1% to 10% of the participants experienced the following:

- Chills, fever;
- Inflammation at the injection site or vein inflammation;
- Increase or decrease in white blood cells

Less than 1% of the participants experienced the following:

- Hearing loss, ringing in your ears
- Life-threatening allergic reactions affecting the skin including reactions known as Stevens-Johnson syndrome and toxic epidermal necrolysis;
- Decrease in platelets (the blood cells that help you clot and stop bleeding after an injury);
- Kidney failure;
- Interstitial nephritis, or inflammation of the spaces between the kidney tubules;
- Pseudomembranous colitis, or antibiotic-associated diarrhea.

Allergic, or allergic-like reaction during or soon after a rapid infusion of vancomycin has been reported and may include the following: low blood pressure, wheezing, shortness of breath, itching, rash, flushing/redness of the upper body or pain and muscle spasm of the chest and back.

This is not a complete list of side effects and others may occur or none may occur at all.

Before participating in this study, tell your study doctor if you are allergic to any drugs, or if you have kidney disease, problems with your hearing, or an intestinal disorder such as inflammatory bowel disease, Crohn's disease, or ulcerative colitis.

### **Risks Associated with Linezolid (Zyvox®)**

Zyvox® has been associated with a decrease of the bone marrow activity and decreases in blood cells, including red blood cells, white blood cells and platelets (the blood cells that help you clot and stop bleeding after an injury). In cases where the outcome is known, when Zyvox® was discontinued, the affected blood cells have increased toward levels before treatment. In this study your study doctor will monitor your blood cell counts using blood tests. You should notify your study doctor if you find that you are bruising unusually easily or bleeding unusually.

In clinical studies, the most commonly reported side effects with Zyvox® were diarrhea, constipation, headache, dizziness, nausea, vomiting, insomnia, fever, and rash. Other side effects reported included oral or vaginal yeast infection, high blood pressure, upset stomach, stomach pain, itching, and tongue discoloration.

Since the drug was approved, additional side effects have been reported though it is not known how common or rare these are. They include symptoms due to low blood glucose (hypoglycemia) in patients treated for diabetes, allergic reaction, seizures, severe skin reactions such as swelling under the skin around the lips and eyes or blistering of the skin around the abdomen, legs and arms, and tooth and/or tongue discoloration. Lactic acidosis (a disorder of metabolism) and damage to peripheral nerves and the optic (eye) nerve have been reported primarily in people that received Zyvox® for longer than 28 days, though have also been reported in people receiving shorter courses of Zyvox®. You must tell your study doctor if you develop repeated nausea or vomiting or changes in vision.

Zyvox® can interact with some other common drugs, including some drugs used to treat depression, Parkinson's disease and drugs used to treat colds and nasal congestion (pseudoephedrine and phenylpropanolamine). Zyvox® should not be taken if you are taking, or have taken in the past 2 weeks, any medicines known as monoamine oxidase inhibitors (for example phenelzine, isocarboxazid, selegiline, moclobemide) any serotonergic psychiatric medicines (for example paroxetine, fluvoxamine, venlafaxine, desvenlafaxine) or other psychiatric or related medicines (for example amitriptyline, desipramine, amoxapine, maprotiline). Zyvox® should not be taken if you have received the medicine fluoxetine in the past 5 weeks. In addition, you may not take any of these medicines until at least 24 hours after your final dose of oral study drug.

Before you receive your first dose of study drug, you must tell your study doctor all the drugs you are currently using, including prescription drugs, non-prescription ("over-the-counter") drugs, herbal medicines and health food supplements. While you are participating in this study, you should not start any new medicines except if they are prescribed by your study doctor.

Zyvox® can interact with a substance in food called tyramine and can result in a rise in blood pressure. You should inform your study doctor if you have a history of high blood pressure. While you are participating in this study, you should not eat large quantities of foods or beverages with high tyramine content. You should have less than 100 mg per meal. Foods high in tyramine content include foods that have undergone aging, fermentation, pickling, or smoking to improve flavor. Examples are:

- aged cheeses (0 to 15 mg tyramine per ounce);
- fermented or air-dried meats (0.1 to 8 mg tyramine per ounce);
- sauerkraut (8 mg tyramine per 8 ounces);
- soy sauce (5 mg tyramine per 1 teaspoon);
- tap beers (4 mg tyramine per 12 ounces);
- red wines (0 to 6 mg tyramine per 8 ounces).

The tyramine content of any high protein food may be increased if the food is stored for long periods or improperly refrigerated.

### **Risks of metronidazole, aztreonam**

The study doctor may also choose to give you another antibiotic. These antibiotics may include Aztreonam and/or Metronidazole and they will be given in addition to the study drug. Aztreonam is an FDA approved antibiotic for the treatment of certain bacterial infections caused by a type of bacteria known as gram negative bacteria. The study doctor may choose to give this drug to you if your infection is one that is caused by a combination of bacteria including gram negative bacteria. Metronidazole is an approved antibiotic for the treatment of certain bacterial infections caused by a type of bacteria known as anaerobic bacteria. The study doctor may choose to give these drugs to you if needed to help your infection symptoms during the study.

Side effects that may occur during the study, based on the experience of others who have received **aztreonam** are reactions that occur at the site of the injection, such as pain and inflammation.

Other side effects include rash, stomach pain, and colitis (inflammation of the colon causing pain and diarrhea). Allergic reactions, some of which can be severe or life threatening, have occurred.

The most common side effects of **metronidazole** include but are not limited to:

- Headache
- Dizziness
- Vaginitis (inflammation of the vagina)
- Stomach and intestinal symptoms including nausea, vomiting, diarrhea, constipation, loss of appetite, and stomach pain or cramps.

Less common or rare side effects of metronidazole include:

- Change in taste sensation
- Dryness of mouth (or vagina or vulva)
- Unpleasant or sharp metallic taste
- Rash
- Fever
- Tingling or numbness in the extremities (arms, legs, hands, and feet)
- Vaginal yeast infection
- Darkened urine

Metronidazole has been shown to be carcinogenic (causing cancer) in mice and rats; however similar studies in hamsters did not show this effect.

### **Risks associated with Any Antibiotic Drug**

Nearly all antibiotics have been associated with diarrhea which may range in severity from mild to life-threatening. If you develop diarrhea, you should notify your study doctor.

### **Allergic Reaction Risks**

People can have allergic reactions to almost any drug. The most common allergic reactions are rashes that appear after taking a medication for several days. The most severe allergic reaction occurs shortly after taking a drug and can result in symptoms such as:

- a rash
- a sudden drop in blood pressure (making you feel dizzy or lightheaded)
- difficulty breathing
- wheezing when breathing
- swelling around the mouth, throat, or eyes
- very fast heart rate
- sweating

Very severe allergic reactions can result in death.

If you develop an allergic reaction, or any reaction that you think is unusual while taking study drug, you should contact the study doctor promptly. If you have any symptoms suggesting a severe allergic reaction, get medical help immediately and let your study doctor know as soon as you can.

Ask the study doctor if you have questions about the signs or symptoms of any side effects you read about in this consent form.

Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study drug.

If you stop your regular medication to be in the study, your infection symptoms might come back or get worse. Please tell the study doctor or study staff right away if you have any problems when you stop taking your regular medication.

### **WHAT ARE THE RISKS OF THE STUDY PROCEDURES?**

Filling out the questionnaires could cause you to feel uncomfortable or upset. Please tell the study doctor or study staff if you feel uncomfortable or upset while filling out a questionnaire.

There is a risk of loss of confidentiality of your information that is used in this study. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

### **What are the risks of receiving study drug by vein (IV infusion)?**

Receiving an IV infusion requires having a small plastic catheter inserted into a vein, typically in your forearm. The study drug is diluted in a small volume of water with salt or sugar and given slowly over approximately 30 or 120 minutes.

Problems that can occur include:

- Placement of the catheter may hurt or may result in a bruise.

- Placement of the needle may make you feel faint or dizzy.
- If the study drug solution goes into surrounding tissues instead of the vein, it can be painful. This is not common.
- Veins containing catheters can become irritated or clotted. In rare cases, an infection can develop and can become serious.

**What are the risks of giving blood for this study?**

Taking blood requires sticking a needle into a vein in your arm. Problems that can occur include:

- The insertion of the needle may hurt or may result in a bruise.
- The insertion of the needle may make you feel faint or dizzy.

There is a slight risk of an infection at the place where the needle is inserted into your arm. You will give about five (5) to eleven (11) tablespoons of blood over the entire study. This is less than a single blood donation, which is approximately 2 cups.

**What are the risks of having an electrocardiogram (ECG)?**

There are generally no risks associated with having an ECG. There is not a risk of shock since this procedure does not give off electricity, but only measures the electrical activities of your heart. It is possible that your skin may become irritated where the tape or sticky pad have been used to connect the ECG wires.

**ARE THERE RISKS IF I OR MY PARTNER BECOMES PREGNANT WHILE I AM PARTICIPATING IN THIS STUDY?**

It is unknown if the study drugs used in this study may harm an unborn child. Some drugs cause women to have their babies prematurely (early) or to have babies with birth defects.

You may not take part in this study if you are pregnant, think that you may be pregnant or are trying to get pregnant or your female partner is trying to get pregnant. Women who are able to get pregnant will be tested for pregnancy before beginning study drug and at a follow-up visit. You also may not take part in this study if you are breast feeding.

**Precautions for WOMEN who can become pregnant**

To participate in this study, you must agree to avoid getting pregnant during the study and through the last study visit. If you are of childbearing potential, you must be abstinent (not have sex) or must simultaneously use two (2) effective birth control methods from the following list, until the last study visit:

- A barrier (condoms, diaphragm or cervical cap) with spermicide;
- A second, different barrier method (condoms, diaphragm or cervical cap);
- Oral or similar contraceptive, which includes, but is not limited to: injectable, implanted or patch hormone therapy, and intrauterine device (IUD);

- Documented surgical sterilization at least 4 weeks prior to your baseline visit;
- Partner vasectomy at least 6 months prior to starting the study.

Note: Females enrolled in the study may not use oral hormonal contraceptives alone since antibiotics have been reported to interfere with their effectiveness. Some methods of birth control will not work when you are taking certain drugs.

You must discuss this with the study doctor.

If at any time during the study through the last study visit, you think you might be pregnant, you must tell the study doctor at once. You will be examined and a pregnancy test performed. If you get pregnant, study drug will be stopped. You will be expected to attend your follow-up visit. You will also be asked later about your health during your pregnancy and about the health of the baby. The study doctor may share this information with the sponsor and Quorum Review (group of people who review research studies to protect the rights and welfare of research participants).

#### **Precautions for MEN and their female partners who can become pregnant**

Men in the study must be abstinent (not have sex) or must use one (1) of the following methods of birth control from the first dose of study drug until after the last study visit:

- Use of a condom for males with a vasectomy (the vasectomy must have been performed at least 6 months prior to the study), or
- Male participants, without a vasectomy or with a vasectomy performed within 6 months prior to enrollment into study, must use a condom and be instructed that their female partner must use another form of contraception such as an IUD, spermicidal foam/gel/film/cream/suppository, diaphragm with spermicide, oral contraceptive, injectable progesterone, subdermal implant or have a tubal ligation if the female partner could become pregnant from the time of the first dose of study medication until after last study visit.

If at any time during the study through the last study visit, you think your female partner might have become pregnant, you must tell the study doctor at once. We (the study doctor and study staff) will ask your partner if we can examine her and perform a pregnancy test. Your female partner will also be asked later about her health during the pregnancy and about the health of the baby. The study doctor may share this information with the sponsor and Quorum Review (group of people who review research studies to protect the rights and welfare of research participants).

It is possible that you could have problems and side effects of the study drugs that nobody knows about yet, which could include your infection getting worse or even death.

#### **WILL BEING IN THIS STUDY HELP ME?**

The study drug may help treat your skin infection. However, this cannot be guaranteed. If the study doctor determines that your skin infection is not responding to the drugs in this study, the study doctor may discontinue use of the study drug and prescribe a different antibiotic.

Information from this study might help researchers come up with new tests or medications to help others in the future.

#### **WHAT IS MY ALTERNATIVE TO BEING IN THIS STUDY?**

Instead of taking part in this study, you may choose to receive an FDA-approved antibiotic treatment recommended by your study doctor. The risks and benefits of this or other treatments will be explained to you by your study doctor, who will answer any questions you have about these other treatments. In addition, you may discuss your options with your regular health care provider if you have questions.

#### **WILL IT COST ME ANYTHING TO BE IN THIS STUDY?**

The study drugs will be made available to you at no charge and you will not be required to pay for any study procedures. You or your insurance company will be billed for medications prescribed to control your infection during the study (metronidazole or aztreonam). You or your insurance company may be billed for any standard medical care that is not required for the research study. You will also be responsible for any additional antibiotics prescribed to you by the study doctor to help control your infection if it does not respond to the study drug.

Before you agree to be in this study and sign this consent form, you should contact your health care payer/insurer to see if your plan will cover the costs required as part of your participation.

#### **WILL I BE PAID FOR BEING IN THIS STUDY?**

<<Quorum will add site-specific compensation language to the form based on information the site reports to Quorum.>>

#### **WHO IS PAYING FOR THIS RESEARCH STUDY?**

The sponsor of this study is Durata Therapeutics, Inc., who is developing dalbavancin. The sponsor is paying the study doctor and other study personnel to conduct this research study.

#### **WHAT IF I GET HURT OR SICK WHILE I AM IN THE STUDY?**

In the event of a research-related injury or illness, necessary medical treatment will be provided to assist in your recovery. The sponsor will pay for any immediate care or treatment that is not covered by your health insurance. The sponsor does not plan to pay for treatment for injury or illness that is not a direct result of the research study. No other financial compensation will be routinely provided in connection with an injury (such as lost wages) other than coverage of the medical treatment of the injury. Be aware that your health care payer might not cover the costs of study-related injuries or illness.

The above statement does not limit any other legal rights that you may have.

### **WHAT IF THERE ARE NEW FINDINGS?**

Your study doctor will tell you in a timely manner of any information learned during the course of this study that may relate to your willingness to continue your participation in this study.

You may be asked to sign a revised consent form if this occurs.

### **WHO CAN I TALK TO ABOUT THE STUDY?**

In the event of an emergency, dial 911 immediately.

If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the study doctor or study staff as soon as possible.

You can ask questions about the study at any time. You can call the study doctor or study staff at any time if you have any concerns or complaints. You should call the study doctor or study staff at the phone number listed on page 1 of this form if you have questions about the study procedures, study costs (if any), study payment (if any), or if you get hurt or sick during the study.

Quorum Review reviewed this study. Quorum Review is a group of people who review research studies to protect the rights and welfare of research participants. Review by Quorum Review does not mean that the study is without risks. If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the study doctor or study staff, if you have a complaint, or if you have general questions about what it means to be in a research study, you can call Quorum Review or visit the Quorum Review website at [www.quorumreview.com](http://www.quorumreview.com).

Quorum Review is located in Seattle, Washington.

Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.

Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

### **DO I HAVE TO BE IN THIS STUDY?**

Your participation in this study is voluntary. You do not have to take part in this study. If you start the study, you may leave the study at any time. You will not be penalized or lose benefits if you do not take part in the study, or if you stop the study at any time. If you decide to stop participation in the study before the last study visit, tell the study doctor.

The study may be stopped by the sponsor or the study doctor, even if you want to continue to participate. You may be asked to stop the study for your safety, because you need additional treatment, or because you do not follow the study instructions.

If your participation in the study is stopped early such as before the last study visit, you may be asked to complete end of study procedures for your safety (such as a final medical examination or blood tests).

### **WHO WILL BE ABLE TO SEE MY MEDICAL RECORD IF I AM IN THIS STUDY?**

The study personnel, the sponsor and its agents and people who work with the sponsor will need to review the medical information collected from you for use in this study in order to accurately record information for this study. In addition, in order to review the study findings, the U.S. Food and Drug Administration (FDA) and other regulatory agencies may review your medical records. The following sections provide a specific description of how your information will be used and disclosed if you participate in this research study. By signing this consent form, you are authorizing such access. If you do not sign this form to authorize access, you will not be able to participate in this research 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, physical exam, electrocardiogram (ECG), blood and urine tests, infection specimen tests, previous drug treatments, etc.
- Information that is created or collected from you during your participation in the study, including photography and the results of the tests and any other procedures performed during the study.
- Information contained in your underlying medical records related to your medical history and treatment.

The above information may identify you by name, address, telephone number, social security number, health plan number, study number, date of birth, dates relating to various medical procedures, and/or other identifying information.

If you sign this form and participate in the study, the study personnel will be authorized to use the information described above to carry out the purposes of the research study. The study personnel will also be authorized to disclose the information described above to the following parties involved in the research study:

- Durata, or agents designated by Durata to collect or review study data.
- Quorum Review
- Government regulatory agencies including the FDA.

Once your information is disclosed to the study sponsors, Quorum or government agencies as described above, there is a potential that your medical information will be re-disclosed and will no longer be protected by US federal privacy regulations. The study data may be transferred to other countries for processing, including countries not covered by Data Protection legislation. The laws of your state may provide further protection.

A description of this clinical trial will be available on <http://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.

The study doctor and study staff are required by law to protect your health information. Other persons who review your health information may not be required by law to protect it and there is a risk that they may share your information with others without your permission.

## **HOW WILL MY STUDY INFORMATION BE USED?**

The information collected about you in this study will be stored both on paper and in computers. In all study records you will be identified only by number and initials, not by name. Your study records, including samples of your blood, will be kept by the sponsor for as long as necessary. The records will be kept confidential and if the results of the study are published, you will not be personally identified.

Your identified personal information will only be used by the persons authorized in this informed consent form for purposes of this research study and related pharmacovigilance (drug safety) requirements.

Data relating to the study, including your medical data that have been entered in coded form, may be processed, which means that they will be collected, entered into computer databases, verified, analysed, printed and reported. Your coded data, and coded samples, will be forwarded by the study doctor to the sponsor and contracted service providers for activities related to the management of the study, such as for example central laboratories. An updated list of companies to whom your coded information will be transferred to is available from PPD (a company that works with the sponsor) and can be accessed upon request through your study doctor.

The results of this study may be used in reports of the study or for scientific presentations or publications, but you will not be identified by name, picture, or any other personally identifying information.

## **Information Rights**

United States law gives you the right to access and control the use of your personal information and to ask for updated information on data recorded. You also have the right to ask for updated information on what data are recorded and to require correction of errors. You should approach your study doctor, who may liaise with the sponsor and its representative, if you have any questions on how your information is processed in the study or if you wish to exercise your rights. However in order to protect the scientific integrity of the study, the study drug you received in this study needs to remain unknown (= blinded) until the study data is analyzed.

If you decide to leave the study:

- No new information will be collected about you. However, the sponsor will need to keep and use any information about you from the research study that has already been collected. They must do this in order to comply with its legal obligations and to keep the scientific integrity of the study.
- You may ask to have any of your stored samples destroyed, if the samples have information that identifies you.

If you agree, your primary care physician/provider will be informed of your participation in this study.

## **AUTHORIZING THE USE OF MEDICAL INFORMATION**

This clinical study may only be performed by collecting and using your medical information. National and international data protection regulations give you the right to control the use of your medical information. Therefore, by signing this form you specifically authorize your medical information to be checked, transferred and processed as follows:

- The authorized representatives of Durata Therapeutics, Inc., monitor(s), auditor(s), the Ethics Committee and regulatory authorities' inspectors may review your medical information by direct access to your medical records.
- Study data, including your coded medical information, and any medical samples taken, may be processed, which means it will be collected, entered into computer databases, verified, analyzed, printed and reported as necessary for legitimate scientific purposes, including use in future medical or pharmaceutical research.

## **RETENTION OF BIOLOGICAL SAMPLES**

Blood samples will be collected, processed, and reported as necessary for the study. Blood samples and microbiology isolates from blood cultures and infection site specimen samples will be retained by Eurofins USA (Eurofins Global Central Laboratory, Inc., [REDACTED] Park Meadow Dr. Suite 110, Chantilly, VA [REDACTED], USA, Tel.: +1 703 480 2500, Fax: +1 703 480 2670) and discarded after approximately 7 years.

Authorised Durata Therapeutics, Inc. personnel and their representatives will have access to the samples and the results.

Any urine specimens submitted for urinalysis are discarded the day that testing is complete. Whole blood for hematology testing is discarded after 7 days and any residual sera and plasma left over after testing is stored for 6 months. Banked serum samples are stored for approximately 7 years and then destroyed. You have the right to be informed of any plans for new analyses on any lab samples that are obtained by the sponsor and have the right to refuse the analysis.

## **WHEN WILL I BE ABLE TO SEE MY MEDICAL AND STUDY RECORDS?**

Under federal regulations you have a right to inspect and obtain a copy of your personal health information, including your medical records and your records in this research study. However, as part of blinding the study and to keep from spoiling the results, you will not be allowed to see your medical or research records while the study is going on. After the study is complete, you have the right to see your personal study data.

If, while you are participating in the study, there is a medical need, the medical professionals who are caring for you may access your research records as needed for your care.

Your authorization to collect, use, and disclose your identifiable health information for the purpose of this research study is also voluntary. However, if you do not give this authorization, you cannot participate in this research study, and, as discussed below, if you withdraw your authorization, you cannot continue to participate.

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This authorization expires in 50 years. In signing this form, you authorize the use and disclosure of your information for purposes of the study until the expiration of this authorization or until you withdraw your authorization.

#### **WHAT IF I CHANGE MY MIND ABOUT BEING IN THIS STUDY?**

At any time during this study, you can change your mind about continuing to participate without penalty or loss of benefit to which you are entitled. If you want to stop being in this study, you should tell the study doctor or study staff. They may ask you some questions about why you have changed your mind.

If you decide to stop participating in this study, study drug will be stopped. If you need additional antibiotic treatment, your study doctor will recommend an approved antibiotic. You should return to the study clinic for your scheduled evaluations. These visits include examinations and tests that will be performed for your safety and at no cost.

You may also end your authorization, or permission, allowing the researchers to collect, use, and disclose your personal health information. To end your authorization, you must notify the study doctor of your decision in writing. If you end your authorization, no new health information will be gathered from you or your existing medical records. However, by government regulations, information that is in your research records at the time that your authorization is ended cannot be removed. You cannot end your authorization for the use of study data that has already been collected. If you revoke your authorization, you will not be able to continue in the study.

You will receive a signed copy of this form.

**SUBJECT'S STATEMENT OF CONSENT AND AUTHORIZATION**

I have read this informed consent form. I have had the opportunity to ask questions and I am satisfied with the explanations provided by the study doctor and study staff. I voluntarily consent to participate in the study and I authorize the use and disclosure of my information in connection with the study as described above. By signing this form, I have not given up any of my legal rights as a research participant. I understand that I will receive a signed and dated copy of this consent and authorization form.

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

**PERSON CONDUCTING INFORMED CONSENT DISCUSSION**

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

\_\_\_\_\_  
Printed Name of Person Explaining Consent

\_\_\_\_\_  
Signature of Person Explaining Consent

\_\_\_\_\_  
Date

I attest that I or my representative discussed this study with the participant named above.

\_\_\_\_\_  
Signature of Principal Investigator or Sub-Investigator