

(Please note: This form is to be customized and printed on each participating clinical site's letterhead or standard Informed Consent template format.)

Patient Information and Informed Consent Form

TITLE: A Phase 3, Randomized, Double-Blind, Double-Dummy Study to Compare the Efficacy and Safety of Dalbavancin to a Comparator Regimen (Vancomycin and Linezolid) for the Treatment of Acute Bacterial Skin and Skin Structure Infections

PROTOCOL NO.: DUR001-302

SPONSOR: Durata Therapeutics, Inc.
89 Headquarters Plaza North, 14th Floor
Morristown, NJ, 07960
USA

INVESTIGATOR: PI Name, Credentials
PI Address

SITE(S): Site/Institution Name
Site Address

STUDY-RELATED

PHONE NUMBER: PI Name, PI Credentials
PI Phone Number
PI Emergency Contact Number (24 hours)

SC Name, SC Credentials
SC Phone Number

You have been asked to volunteer 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 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 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 treatment of skin and nearby tissue infections. "Investigational" means that the drug being tested in this study has not been approved by the Food and Drug Administration (FDA) in the USA, or any Health Authority throughout the world and 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 medications as vancomycin and teicoplanin, two commonly used and 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.

PURPOSE AND OVERVIEW OF THE STUDY

You have been asked to volunteer to participate in this research study of an investigational drug called dalbavancin because your doctor has determined that you have an infection of your skin and nearby tissues that requires antibiotics. The purpose of this research study is to determine if dalbavancin is safe and at least as effective as standard treatment for skin and nearby tissue infections.

As of 12 Nov 2010, dalbavancin has been given by injection into a vein (administered intravenously, or IV) to 1292 patients who participated in 14 clinical studies. The results have shown that dalbavancin is at least as effective as different comparator antibiotics. It is expected that approximately 556 patients will be enrolled in this study worldwide.

In this study, dalbavancin is being compared to intravenous (IV) vancomycin, which is approved in the U.S. by the FDA for the treatment of bacterial skin and nearby tissue infections. You will be assigned by chance to receive either IV dalbavancin plus placebo (a treatment that contains no active ingredients) or IV vancomycin (every 12 hours) plus placebo.

You will have an equal (“50/50”) chance of being treated with either drug, like flipping a coin.

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 you are getting better, you may be switched from the every 12 hours IV treatment to an oral therapy with a 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 approved by several European and Asian Regulatory Authorities and 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.

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 office/clinic evaluation 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 informed consent form and you will be asked if you agree to participate in this study. Nothing further will happen unless you consent. 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 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 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, 15 mL) for routine lab tests;(including hematology, serum chemistry, hs-C-reactive protein levels, and ASO/anti-DNase titers),

- 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 20 mL, each, for a total volume of 40 mL) 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 treatment initiation, 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 (total volume of 160 mL).

Some of your blood from this visit and from the Day 3 visit will be stored and 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 the way you are currently being treated for your condition. Your stored samples for this study will be maintained at Eurofins Global Central Laboratory, Inc., 14100 Park Meadow Dr., Suite 110 Chantilly, VA 20151, USA, Eurofins SG (Eurofins Global Central Laboratory Singapore, 1 International Business Park, #01-16 The Synergy, Singapore 609917 Tel.: +65 6562 3858, Fax: +65 6562 3086) and SRL Medisearch Inc., 1-3-14 Tana-Shioda, Chuo-ku, Sagamihara-Shi, Kanagawa 252-0245, Japan Tel: +81 42 777 6685, Fax: +81 42 777 2220

- for approximately 7 years after study completion, then destroyed. Stored blood will not be used for genetic testing.
- 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;
- A blood hormone test will be performed for women who are post-menopausal and < 50 years of age or ≥ 50 years of age who have been post-menopausal for < 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).

Treatment Period

DAY 1

- At this visit, you will be given your first doses of study drug by IV infusion (by vein);
- Infusions 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 (by vein) approximately 12 hours apart;
- You will have your vital signs measured,
- 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 15 mL) for routine lab tests;
- Some of your blood will be stored and may be used for future safety or other testing. Stored blood will not be used for genetic testing.
- 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 (by vein) 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 (by vein) 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 – DAY 7

- On these days, you will be given two doses of study drug by IV infusion (by vein) or a pill by mouth, approximately 12 hours apart as determined by your 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 two doses of study drug: one dose by IV infusion (by vein) for 30 minutes, followed by one dose by IV infusion over two hours or a pill by mouth as determined by your doctor.
- Approximately 12 hours later, you will receive another two hour infusion of study drug or a pill by mouth as determined by your doctor.

DAY 9 – 14

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

End of Treatment Visit

Day 14 or 15, possibly Day 16 for some patients (or within 3 days after stopping treatment 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 15 ml) for routine lab tests;
- 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 (by vein) 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 10 mL) for routine lab tests;
- If you are a female capable of getting pregnant, a urine sample for pregnancy testing will be collected;
- 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 , and about any other 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 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 of your other medicines or vitamins during the study. You may also be asked to keep track of the dates, times and how much of these medicines you took while at home and bring this information back to your study doctor's office for review.

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.

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. Regardless of which treatment you are assigned to receive (vancomycin 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 treatment options in previous studies of dalbavancin included nausea, diarrhea and headache, which were reported less frequently in dalbavancin-treated patients than in patients receiving the comparison study drug. Treatment-related side effects (considered possibly or probably related to study drug) were reported by a smaller number of dalbavancin-treated patients than patients treated with a comparator drug. Treatment-related side effects that occurred in 1% or more of dalbavancin-treated patients 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 studies, increases or decreases in blood sugar (glucose) were more common in patients treated with dalbavancin compared to patients receiving the comparison study drug. In addition, abnormal liver function

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

Some previous study patients had to discontinue study treatment due to side effects. The most common side effects resulting in patient discontinuation included rash and itching. These side effects were seen at a similar frequency in patients taking dalbavancin as patients 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 patients with leukopenia got better and did not stop taking study medicine.

In summary, the most common and expected treatment-related side effects reported by patients in previous studies included:

- (percentage of the study patients 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 %

The majority of side effects reported in previous studies were mild or moderate in severity. 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 dalbavancin treated patients). In previous studies with dalbavancin, this infection was moderate in severity. In previous studies, increases (0.6%) or decreases (0.5%) in blood sugar (glucose) were more common in patients treated with dalbavancin compared to patients receiving the comparison study drug.

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

More serious reported side effects in dalbavancin treated patients 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 patients with leukopenia got better and did not stop taking study medicine.

Risks Associated with Vancomycin

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

More than 10% of the patients experienced the following:

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

1% to 10% of the patients 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 patients 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

An 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 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 allergic reaction, seizures, and 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 patients that received Zyvox® for longer than 28 days, however it has also been reported in patients 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 associated with Any Antibiotic Treatment

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.

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:

- 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.

WHAT ARE THE RISKS OF THE STUDY PROCEDURES?

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 water with salt or sugar and given over 30 to 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 at least 80 mL to maximum 210 ml of blood over the entire study. This is less than a single blood donation, which is approximately 500ml.

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.

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.

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.

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 patients, 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, sub dermal 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 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.

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 treatment in this study, the study doctor may discontinue use of the study drug and prescribe a different antibiotic.

WHAT IS MY ALTERNATIVE TO BEING IN THIS STUDY?

Instead of taking part in this study, you may choose to receive an 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.

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 may be billed for any standard medical care that is not required for the research study.

WILL I BE PAID FOR BEING IN THIS STUDY?

You will not receive payment for participating in this study, but 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 could be reimbursed (on production of a receipt) for certain additional costs incurred (such as travel), which relate to your participation in the trial.

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?

Compensation for study-related injuries will be in accordance with [national] legislation. Your study doctor will explain how you can obtain a copy of these guidelines.

In the event of a research-related injury or if any other problems arise, please contact [investigator name] at [tel. No.].

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 or your legally acceptable representative 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?

You may ask questions about this consent form or the study at any time (before or during the study). For questions about the research study or if you experience a research-related injury, contact:

[Insert Name and contact information]

If you have complaints or questions about your rights as a research subject, you may contact the Institutional Independent Ethics Committee (IEC). An IEC is a group of scientific and non-scientific individuals who review research studies with the safety and welfare of research subjects in mind. You can contact the IEC at:

[IEC contact information]

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 and follow instructions.

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 rules.

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?

Information collected and processed

As part of this study, your study doctor, nurses, and other study staff will maintain paper and electronic records about you. Basic personal information will be recorded including your name, contact details, gender, racial origin, date of birth and weight. Your racial origin will be collected only for purpose of clinical research.

Information on your medical history will be collected, as well as clinical information relating to your participation in the study, including how you have responded to the study drug, any side effects you may have experienced, and the results of any tests performed during the study. You will not be able to take part in this study if you do not consent to the collection of this information about you.

To ensure that your personal information is kept confidential, your name and any other information that would allow you to be identified will not be recorded or included in any forms, records or samples that your study doctor provides the sponsor. Instead, you will only be identified by a code. Only the study doctor and authorized subjects will have permission to connect this code to your name, by a list that will be kept securely by the

hospital/institution for a period of at least 15 years, according to applicable laws. Your coded medical information will be kept by Durata Therapeutics, Inc. for 10 years.

Parties involved

The information collected about you will be held by <<*add name of institution*>>.

The following people and groups of people may also look at your medical records (direct access) to make sure that the study is being done properly and to check the quality of the data in the clinic:

- Study monitors and auditors, who may work for the sponsor Durata Therapeutics or the contract research organization <<PPD local company name>> (“PPD”) appointed by Durata Therapeutics;
- Ethical committee that supervises the conduct of the study to ensure that your rights and well-being are looked after;
- National and international government agencies involved in keeping research safe for people

In these circumstances your identity may become known. By signing this consent form, you authorize these groups to have a direct access to your medical records and study records.

For the purposes of compliance with European and national data protection law <<*insert national law reference*>>, Durata Therapeutics, Inc. based in the US and <<*add name of institution*>> shall be responsible as Controllers for ensuring that necessary legal protections for your personal data are applied by all parties involved in the study.

As is legally required for a non-European Union based Controller, Durata Therapeutics, Inc. has appointed <<*PPD local company name and address*>> as its representative in your country to ensure that its responsibilities under data protection law for this study are fulfilled.

Purposes

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, analyzed, 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 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.

Transfer of information

Some of the recipients of your identified or coded data may be based in countries do not afford the same level of protections for personal data as in your country. However, Durata Therapeutics, Inc. and any third parties it contracts will keep any information they receive as confidential as possible within the limits of the law. Your study data may also be transferred to foreign Health Authorities in condition that will guarantee confidentiality.

Information Rights

European and national protection 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 treatment you received in this study needs to remain unknown (= blinded) until the study data is analyzed.

Leaving the study

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.
- The study data may be transferred to other countries for processing, including countries not covered by data protection legislation

RETENTION OF BIOLOGICAL SAMPLES

Blood samples will be collected, processed, and reported as necessary for the study. Blood samples will be retained by Eurofins SG (Eurofins Global Central Laboratory Singapore, 1 International Business Park, #01-16 The Synergy, Singapore 609917 Tel.: +65 6562 3858, Fax: +65 6562 3086 and SRL Medisearch Inc., 1-3-14 Tana-Shioda, Chuo-ku, Sagami-hara-Shi, Kanagawa 252-0245, Japan Tel: +81 42 777 6685, Fax: +81 42 777 2220) for a period of approximately 7 years. Microbiology

isolates from blood cultures and infection site specimen samples will be retained by Eurofins USA (Eurofins Global Central Laboratory, Inc., 14100 Park Meadow Dr. Suite 110, Chantilly, VA 20151, USA, Tel.: +1 703 480 2500, Fax: +1 703 480 2670) and discarded after 7 years.

Authorized 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 a maximum of 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.

ETHICAL REVIEW

The Ethics Committee has given this study a positive opinion.

The study personnel, the sponsor and its agents and PPD 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, PPD or other agents designated by Durata to collect or review study data.
- The Institutional Review Board (IRB) or Independent Ethics Committee (IEC) that oversees the research study at your site.
- Government regulatory agencies including the FDA.

Once your information is disclosed to the study sponsors, the IRB/IEC 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 [Insert your state country law] may provide further protection.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

Dr. [Site to Insert PI Name] is 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 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.

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.

This authorization has no expiration date. In signing this form, you authorize the use and disclosure of your information for purposes of the study at any time in the future.

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

Taking part in this research study is voluntary. You may decide not to take part or withdraw at any time during the study without penalty or loss of benefits to which you are otherwise entitled. However, it might be helpful if you could explain the reason for your withdrawal to your study doctor. If you end your participation, you may receive standard treatment and no prejudice will be shown towards you for medical care or participation in

future research studies. In addition, your study doctor or the pharmaceutical company may withdraw you from the study, without your consent:

- if you need additional medication,
- if you violate the study plan,
- if you experience a study-related injury, or
- for administrative reasons.

If you should withdraw from the study, you should go through the termination procedures (medical examination and laboratory tests) for your own safety.

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

If you agree to participate in this study, 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.

SUBJECT'S STATEMENT OF CONSENT AND AUTHORIZATION

TITLE: A Phase 3, Randomized, Double-Blind, Double-Dummy Study to Compare the Efficacy and Safety of Dalbavancin to a Comparator Regimen (Vancomycin and Linezolid) for the Treatment of Acute Bacterial Skin and Skin Structure Infections

PROTOCOL NO.: DUR001-302

I have read and understand the statements in this informed consent form. I have had the opportunity to ask questions and I am satisfied with the explanations provided by the consent process. I voluntarily consent to participate in the study and I authorize the use and disclosure of my information in connection with the study as above described. I specifically consent to the transfer of my personal data to other countries for processing, including countries not covered by data protection legislation

I understand that I will receive a signed and dated copy of this consent and authorization form.

SUBJECT

Printed Name of Subject	
Signature of Subject	Date of Signature Handwritten by Subject

LEGALLY AUTHORIZED REPRESENTATIVE

Printed Name of Legally Authorized Representative	

_____ Signature of Legally Authorized Representative	_____ Date of Signature Handwritten by Legally Authorized Representative
<i>Describe the Representative's authority to act for the subject or relationship to Subject:</i>	

PERSON CONDUCTING INFORMED CONSENT DISCUSSION

_____ Printed Name of Investigator	
_____ Signature of Investigator	_____ Date of Signature Handwritten by Investigator