

INFORMED CONSENT TO PARTICIPATE IN CLINICAL RESEARCH STUDY

Evaluation of Pharmacokinetics, Safety and Tolerability of a Single 1000 mg Intravenous Dose of Dalbavancin in Healthy Japanese Subjects

Sponsor: Durata Therapeutics, Inc.

Protocol Number: DUR001-103
May 12, 2011

Principal Investigator: Mark Yen, M.D.
("Study Doctor") California Clinical Trials Medical Group
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Glendale, CA 91206

24-Hour Telephone Number: (800) 239-4367

References to the "study doctor" include the study doctor and any assistants, employees, or other staff acting under the supervision and at the direction of the study doctor.

This consent may be hard to understand in places. Please ask questions if there are parts you do not understand.

This is a clinical trial (a type of research study). Clinical trials include only individuals who choose to take part. Please take your time to make your decision. Discuss it with your friends and family. Be sure to ask questions about anything you don't understand.

PURPOSE & DESCRIPTION OF THE STUDY

You, _____, have been asked to participate in a research study (the "study") to evaluate dalbavancin, an experimental drug being studied as a possible treatment for bacterial skin infections. Dalbavancin has not been approved by the U.S. Food and Drug Administration.

PURPOSE: The purpose of the study is:

- to evaluate the safety and tolerability of a single dose of dalbavancin when given by intravenous (IV) infusion (solution slowly released into the vein of your arm) in healthy Japanese subjects
- to evaluate the pharmacokinetics (how the body handles the drug) of a single IV dose of dalbavancin in healthy Japanese subjects.

HOW LONG WILL I BE IN THIS STUDY?

Approximately 12 subjects will be selected for this study at one study site. Once all screening evaluations have been completed (which could take up to 27 days), you will be in the study for approximately 29 days.

The study doctor may decide not to admit you into the study or may discontinue your participation in the study at any time (for example, if the study doctor feels your health may be at risk, if the Sponsor decides to discontinue the study for any reason, or if you do not follow the instructions given by the study doctor).

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study doctor and your regular doctor first.

WHAT IS INVOLVED IN THE STUDY?

Screening Evaluation: To determine if you meet the conditions for participation in the study, the study doctor will perform, at no cost to you, a screening evaluation. You will be asked to fast for at least 8 hours before arriving at the study unit for the screening visit. This will include:

- an appropriate medical and medication history
- a physical exam
- vital signs (blood pressure, pulse, temperature, breath rate)
- measurements of your height and weight
- an electrocardiogram (ECG – a study of the electrical activity of the heart)
- laboratory tests (blood and urine), including also the following:
 - a blood pregnancy test (for females)
 - a follicle-stimulating hormone (FSH) test (for postmenopausal females to verify that you are not able to become pregnant)
 - hepatitis (liver) test(s)
 - an HIV test
 - a urine drug screen
 - alcohol breath test

If your HIV test result is positive, you will not be eligible to participate in the study and we will be legally required to report it to the health authorities (e.g., Los Angeles County Department of Public Health). The results of your HIV test will be kept confidential, except as required by law, with your other study files as outlined in this consent form. While expected to be confidential, these results, if disclosed, may affect your employment or health insurance options. If your HIV test result is positive, a repeat test should be done for verification. The sponsor will not pay for the repeated test or any follow-up medical care or counseling for HIV positive results or AIDS. However, the study doctor can provide you with referral information to doctors who can perform the repeat test and medical follow-up and counseling, as appropriate.

Other tests may need to be performed in order to consider your eligibility for this study.

Inclusion Factors: In addition to meeting the conditions determined by the above exams and tests, you may qualify for this research study if you are a healthy Japanese male or female between 18 and 55 years of age. For this study, Japanese subjects must:

- Have both parents and both sets of grandparents must be Japanese
- have been born in Japan
- have a valid Japanese passport
- have not lived outside of Japan for more than 5 years
- live in the Japanese community, eating a typical Japanese diet with a lifestyle not notably different from that experienced in Japan

Women must be either physically unable to become pregnant or must use an acceptable method of birth control from the start of the study until 60 days after receiving study drug. At no point during the study may you attempt to become pregnant or breast-feed. You will be given a pregnancy test to verify that you are not pregnant before you are allowed to enter the study.

Men must use an acceptable method of birth control from the first day of dosing until 60 days after receiving the study drug.

Exclusion Factors: Even if you meet other qualifications for participating in the study, you will be excluded if the study doctor determines that you have any condition that might make the study harmful to you or interfere with the study results.

You will not be allowed to enter the study if you must take medications not allowed by the study, if you have taken alcohol, drugs of abuse, or certain medications in a time period considered unacceptable by the study doctor, or if you have a history of alcohol or drug abuse within the past 2 years.

Once all screening evaluations have been completed and if you qualify and agree to be in the study, the actual study period will last for at least 29 days, including a 4-day/3-night stay in the study unit, three (3) safety follow-up visits, and an end-of-study visit.

The visit schedule is described below. If you qualify for the study the following will occur.

Admittance Day (Day -1)

You will be asked to come to the study unit the day before dosing to begin your stay. You will be required to fast overnight for 8 hours before arriving at the study unit in the morning. The following procedures will be performed on this day:

- admittance to the study unit;
- a review of your current medical information to confirm that you are still eligible to participate in the study;
- physical exam;
- vital signs;
- an ECG; and
- laboratory tests (blood and urine), including also the following:
 - a blood pregnancy test (for females)
 - a urine drug screen
 - alcohol breath test

Throughout the study, you will be asked how you are feeling and about any medications you may have taken.

Day 1

The following procedures will be performed on this day:

- vital signs;
- a blood sample will be collected before study drug is given;
- study drug will be given (see section on the study drug later in this document); and
- multiple blood samples will be collected over the next 12 hours to measure the amount of study drug in your blood.

Day 2

The following procedures will be performed on this day:

- vital signs; and
- a blood sample will be collected to measure the amount of study drug in your blood.

Day 3 (Discharge)/Early Termination

The following procedures will be performed on this day:

- vital signs;
- a blood sample will be collected to measure the amount of study drug in your blood; and
- you will be discharged from the study unit.

Follow-Up Visits (Day 7, Day 14, and Day 21)

You will be asked to return to the study unit for safety follow-up visits on Day 7, Day 14, and Day 21. You will be required to fast for at least 8 hours before arriving at the study unit on Day 7. The following procedures will be performed on one or more of these days:

- vital signs;
- physical exam;
- laboratory tests (blood and urine); and
- a blood sample will be collected to measure the amount of study drug in your blood.

Day 28 (End-of-Study Visit)

You will be asked to return to the study unit on Day 28 for the End-of-Study visit. You will be required to fast for at least 8 hours before arriving at the study unit. The following procedures will be performed on this day:

- vital signs;
- physical exam;
- measurement of your weight;
- laboratory tests (blood), including also a blood pregnancy test for females; and
- a blood sample will be collected to measure the amount of study drug in your blood.

You may be required to stay in the study unit longer or have additional clinic visits if the study doctor believes it is in your best interest. The above tests may need to be repeated or additional tests may need to be performed for your continued participation in the study.

During the study your blood will be drawn by either a catheter (a small plastic tube) or a needle. If the catheter does not work well, you will need to have several needle sticks to obtain the necessary blood samples.

There are certain restrictions regarding scheduling of clinic visits, taking the study drug, diet, alcohol, exercise, and fasting (no food or drink except water) that you will need to follow during the study. The study doctor will provide you with specific instructions to ensure you are fully informed about the above noted restrictions, and any other requirements for the study.

While you are in the study, you will be required to follow a precise schedule. You must not take any other medications including over-the-counter and herbal (including homeopathic) medications during the study without the express approval of the study doctor.

Upon completion of your study participation, it is your obligation to arrange for routine medical and/or psychiatric care with a personal medical doctor. California Clinical Trials Medical Group does not provide any continuing care. A list of professional providers will be made available to you upon request.

INFORMATION ABOUT THE STUDY DRUG

The study drug will be given as an IV infusion on Day 1. An IV catheter will be inserted into the vein of your arm and a solution will be slowly released into your vein over a 30 minute period. The IV line will be flushed with a saline solution at the end of the infusion.

If you qualify for the study, you will be assigned by chance (like the flipping of a coin) to receive one of the following doses during the infusion:

- (1) solution containing 1000 mg dalbavancin; or
- (2) placebo solution (a solution that has no active drug in it)

You have a 5 out of 6 chance of receiving dalbavancin and a 1 out of 6 chance of receiving placebo. Because of the type of study in which you are participating, neither you nor the study doctor will know whether you are receiving dalbavancin or placebo. This information is available should it become medically necessary as determined by the study doctor.

RISKS AND DISCOMFORTS

Your participation in this study involves some risks and discomfort. In addition, if you have not been completely truthful regarding your health history, or if you do not completely follow the directions given to you, you may increase the chance of harming yourself by being in this study.

So far 1292 people have received dalbavancin in various clinics and hospitals throughout the U.S.

Side effects most frequently reported in association with dalbavancin include:

- diarrhea
- nausea
- vomiting
- headache

Side effects less frequently reported in association with dalbavancin include:

- constipation
- rash
- itching
- high liver enzyme level
- high or low blood sugar level
- low white blood cell count

You are strongly advised to ask the study doctor about any side effects you do not understand.

The preceding lists of side effects represent a wide range of possibilities, but it is possible that you may not experience any of them; however, it is possible that you may experience other symptoms or side effects that are unforeseen or have not been observed frequently in connection with use of dalbavancin. As dalbavancin has not been given to large numbers of subjects, it is possible that unexpected side effects which are potentially life threatening could occur.

Some of the testing and procedures that will be performed during the study may also have side effects. For example, blood sampling may result in swelling, pain, bruising, redness, or infection where the needle is inserted. The total amount of blood drawn from you over the course of the study will not exceed the amount of blood normally donated by an individual during a single visit to a blood bank (approximately one pint). The adhesive patches on your chest for ECG monitoring may cause redness, rash, itching, or blisters.

At all times over the course of the study, you will be required to promptly contact the study doctor by telephone at (800) 239-4367, or the nurse while you are in the study unit, if you experience symptoms or side effects. If any of your symptoms or side effects are unexpected (have not been described to you in this consent form), or are severe or alarming, you will be required to report them to the study doctor immediately, day or night.

Pregnancy risks

It is unknown if the study drug 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 the 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 for 60 days after receiving study drug. 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 60 days after receiving study drug:

- A barrier (condoms, diaphragm or cervical cap) with spermicide;
- 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 and through 60 days after receiving study drug, 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 60 days after receiving study drug:

- Use of a condom for males with a vasectomy (the vasectomy must have been performed 6 months prior to the study), or
- Males 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 should use another form of contraception such as an IUD, spermicidal foam/gel/film/cream/suppository, diaphragm with spermicide, oral contraceptive, injectable progesterone, subdermal (under the skin) implant or have tubes tied if the female partner could become pregnant from the time of the first dose of study drug until 60 days after receiving study drug.

If at any time during the study until 60 days after receiving study drug, 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.

For more information about risks and side effects, ask the study doctor.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

There is no direct medical benefit to you for participating in this trial. However, your participation will assist in the search for a new treatment for certain bacterial skin infections.

ALTERNATIVE TO STUDY PARTICIPATION

This study is not intended to treat any medical condition. Your alternative to participation is not to participate in this study.

CONFIDENTIALITY

Information obtained during the course of the study will be retained in confidential files at California Clinical Trials Medical Group; however, data which contains your identity will be subject to disclosure in certain circumstances. The sponsor may use the data to seek approval from the U.S. Food and Drug Administration to market dalbavancin. At any time during or after the study, representatives of the U.S. Food and Drug Administration, members of the independent review board, representatives of PAREXEL International (the company helping the study doctor to conduct the study), or the sponsor may inspect the files and your medical records. On rare occasions, the law may also require disclosure to regulatory bodies or other third parties, for instance, if you are found to have a reportable disease such as hepatitis. At the study doctor's discretion, information about your participation in the study may be given to your family or health care providers in appropriate situations.

You may be asked to provide medical records for surgeries or medical treatment you had prior to the study in order for the study doctor to fully review your medical history.

Data from the study may be used in scientific presentations or reports, although your identity will not be revealed. Your medical information may be held and processed on a computer.

When you are admitted to the study unit, it is necessary for the study staff to review and log in your belongings for your protection as well as the protection of others.

It is important that the study itself remains confidential and that any accidental release of confidential information about the study is prevented. Before the study has begun, you are encouraged to discuss with friends and family to help you decide whether you want to participate. However, you should refrain from publicly disclosing details of the study (for example, the name of the sponsor, the study drug, any information regarding other study participants, or the study procedures). You are also not allowed to post or discuss these details of the study in any public forum, such as on social networking sites or blogs.

By signing this Informed Consent you specifically authorize disclosure in all the circumstances just described.

WHAT ARE THE COSTS?

There is no charge to you for your participation in the study. The results of routine medical tests performed by the study doctor will be provided to you or your personal medical doctor upon receipt of written authorization for release, or as medically required. The services provided and evaluations performed by California Clinical Trials Medical Group are limited and should not be considered a substitute for a thorough evaluation, ongoing medical care, or follow-up by your personal physician.

INVESTIGATOR PAYMENT

The sponsor is paying the study doctor and the study site for conducting this study.

WHAT HAPPENS IF YOU HAVE COMPLICATIONS OR ARE INJURED?

If you have serious side effects, complications or are injured as a result of participating in this study, the sponsor, Durata Therapeutics, Inc., in consultation with the study doctor, will pay the reasonable and customary costs of such treatment if it is determined that the untoward event occurred as a result of study participation, and the costs of treatment are not covered by any other health insurance, government health program, or other third party providing coverage for health care.

Neither financial compensation nor reimbursement for such things as pre-existing conditions, illness or disease unrelated to study drug, lost wages, property damage, disability, or discomfort is offered. It is your obligation, in the event you feel impaired in any way, to cease activity that may cause injury to yourself, to any other person, or to property as a result of participating in this study (e.g., driving a vehicle, operating machinery, climbing a ladder).

WILL YOU BE COMPENSATED DURING THE STUDY?

As compensation for time and travel for being in this study, you may receive up to one thousand six hundred seventy dollars (\$1,670.00). You will be compensated \$110.00 for the Screening Evaluation Visit, \$250.00 for each day in the study unit, \$140.00 for each follow-up visit, and \$140.00 for the End-of-Study visit. If you qualify, based on the screening procedures (described above), and you begin the study and complete the study, this compensation will be paid about 1 week after your final visit and all study and/or health issues, if any, are resolved. If you withdraw, or if you are removed from the study before completion for any reason, you will receive a pro-rated amount of compensation based on the visits you have completed.

Alternates

You may be chosen as an alternate in this study. If you are chosen as an alternate you may be asked to remain on the unit for up to 2 days and 1 night. You will be asked to follow the regular check-in procedures. If you are chosen as an alternate and you continue to qualify but are not enrolled into the study, you will receive the stated compensation amount above for each study day completed.

YOUR RIGHTS AS A RESEARCH SUBJECT

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Declining or leaving the study will not result in any penalty or loss of benefits to which you are entitled.

If you decide to end your participation in the study, you should contact the study doctor who will explain the best way for you to withdraw. The study doctor will explain the reason for additional tests and examinations which may be indicated for anyone who wishes to withdraw from the study. If you end your participation in the study early, you should contact your personal treating physician so he or she can provide you with the best course of continuing care.

The study doctor will tell you about any significant new information developed during the course of the study which may influence your willingness to continue participation.

WHO TO CALL IF YOU HAVE QUESTIONS

For questions, concerns or complaints about the study or a research-related injury, contact **Dr. Mark Yen** at **(800) 239-4367**, at the address on page one of this consent, or at the study doctor's mailing address: 1560 East Chevy Chase Drive, Suite 140, Glendale, CA 91206.

This study was reviewed by Aspire Independent Review Board (IRB). An IRB reviews research to protect the rights and welfare of study participants. If you have problems, concerns, suggestions, questions or information about the study, and for information regarding research subject's rights, please call Aspire's Quality Assurance and Compliance Administrator at 1-877-366-5414 (toll free).

Aspire Independent Review Board is a group of people who perform independent review of research with the rights and welfare of the participants in mind. While Aspire IRB has approved this research, only you can decide if participation is the right choice for you.

SIGNATURE AND CONSENT TO BE IN THE STUDY

SUBJECT'S CONSENT TO PARTICIPATE

I received a copy of the "Experimental Subject's Bill of Rights" prior to receiving this consent form and had the opportunity to review it.

I have read this consent form and will be given a signed and dated copy of it. I have also been given the opportunity to ask any and all questions I had about the study and all the questions I asked were answered to my satisfaction. I have been informed of the risks and benefits of participation as described in this document. By signing this consent form, I freely consent to be administered dalbavancin or receive placebo under the study doctor's direction.

My consent to participate in this research study does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved with this study. Nothing in this consent form is intended to change any applicable federal, state, or local laws regarding informed consent.

PRINTED NAME OF SUBJECT

SIGNATURE OF SUBJECT

DATE

PRINTED NAME OF WITNESS

SIGNATURE OF WITNESS

DATE

PRINTED NAME OF PERSON OBTAINING CONSENT

SIGNATURE OF PERSON OBTAINING CONSENT

DATE

CALIFORNIA CLINICAL TRIALS
AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

**Evaluation of Pharmacokinetics, Safety and Tolerability of a Single 1000 mg
Intravenous Dose of Dalbavancin in Healthy Japanese Subjects**

Purpose of This Consent Form

This authorization form describes the use and disclosure of your health information which is collected for the clinical study in which you are participating.

By signing this consent form, you are giving the study doctor permission to use and disclose your study-related health information as described in this consent form. You do not have to give permission for this use and disclosure of information. However, if you do not, you will not be able to participate in the study.

What is Your Health Information?

The study doctor and study staff will obtain and record your health information during the study. This information includes your medical and/or psychiatric history, the treatment you receive during the study, and the results of examinations and tests done during the study. This information can be found in your medical records, medical chart, and study forms.

Review of Your Health Information

At any time during or after the study, the sponsor of the study, Durata Therapeutics, Inc., representatives of PAREXEL International (the company helping the study doctor to conduct the study), representatives of government agencies such as the Food and Drug Administration, and members of the institutional review board (an independent review board who serves to protect subject welfare), may inspect your medical records, medical chart, and study forms. This review of your health information will typically take place at the hospital or clinic where the information is kept. The review may involve viewing your full name and other health information which identifies you. However, as described in the next section, your information will be de-identified (altered or abbreviated so that your identity is not revealed) before it is sent to the sponsor.

You have the right to request access to your health information related to the study for as long as this information is held by California Clinical Trials Medical Group. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study has been completed.

Use and Disclosure of Your Study Related Health Information

Your health information that is relevant to the study is sent to the sponsor on specific study forms. Your full name will not appear on the study forms, only your initials and subject identification number. However, the study forms will contain other information about you, such as your age, sex, and medical history. It is possible that this other information could be used to identify you even though your name does not appear. The study doctor will send the sponsor only the information needed for the study.

The information collected about you and sent to the sponsor may be used in many ways. The sponsor may use the data to analyze and make conclusions about the results of the study, report side effects to government health agencies or other doctors, and possibly seek approval from government health agencies throughout the world (e.g., the FDA) to market dalbavancin. The sponsor may also reanalyze the study results in the future or combine your information with information from other similar studies. Both the study doctor and sponsor may use study information to prepare scientific presentations or reports.

While using the information in these ways, the sponsor may give it to its affiliated companies in the U.S. or other countries. The sponsor may also share the information with its business partners or companies it hires to provide study-related services.

Once the information is sent to the sponsor, it will no longer be protected by U.S. federal privacy laws and the sponsor could use or disclose it in ways other than those listed here. However, your name will not appear in any sponsor reports, databases, or publications, or in any future disclosures by the sponsor.

Authorization Expiration

This authorization to use and disclose your health information will expire 50 years from the date of your signature on this form. The study doctor may need to add to or correct information about you even after your study participation is over. This could include providing updates of your health status if that is important to the purpose of the study. The review of your medical records (described above) may also take place after the study is over.

Revoking (Canceling) Authorization to Use and Disclose Your Health Information

You may change your mind and revoke (cancel) this authorization at any time. Revoking your authorization means taking back the permission you gave the study doctor to use and disclose your health information as described in this consent form.

If you revoke your authorization, the study doctor will not collect any new health information about you unless the information concerns an adverse event (a bad effect) related to the study. However, the study doctor can continue to use and disclose any already collected information as necessary to maintain the integrity or reliability of the study. All information that has already been collected for study purposes and any new information about an adverse event related to the study will be sent to the sponsor. Even if you revoke this authorization, the sponsor can still keep and use any information that it has already received.

You may revoke your authorization at any time. Revoking your authorization must be done in writing. If you want to revoke your authorization, you can write a letter to the study doctor. However, once you do so, you can no longer continue to participate in the study.

Subject's Consent to Authorize Use and Disclosure of Health Information

I have read this authorization form and will be given a signed and dated copy of it. I have also been given the opportunity to ask any and all questions I have about the use and disclosure of my health information. By signing this form, I permit the study doctor to use and disclose my health information as described in this authorization form.

PRINTED NAME OF SUBJECT

SIGNATURE OF SUBJECT

DATE

PRINTED NAME OF WITNESS

SIGNATURE OF WITNESS

DATE

PRINTED NAME OF PERSON OBTAINING CONSENT

SIGNATURE OF PERSON OBTAINING CONSENT

DATE