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APPROVED: 2-5-08

COPERNICUS GROUP IRB



**SUBJECT INFORMATION AND CONSENT FORM AND AUTHORIZATION TO USE
AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH**

Name of Research Study: A Phase 2, Multi-Center, Randomized, Open-label, Comparative Study to Evaluate the Efficacy and Safety of Intramuscular Ceftaroline versus Intravenous Linezolid in Adult Subjects with Complicated Skin and Skin Structure Infections

Protocol Number: P903-19

Sponsor: Cerexa, Inc.

Principal Investigator: «FirstName» «MiddleName» «LastName» «Suffix»

Address(es):

«Company»	«Company2»	«Company5»
«Address» «SuiteDept»	«Address2»	«Address5»
«City» «State» «Zip»	«City2» «State2» «Zip2»	«City5» «State» «Zip5»
«Company3»	«Company4»	
«Address3»	«Address4»	
«City3» «State3» «Zip3»	«City4» «State4» «Zip4»	

Daytime telephone number(s): «Phone»

24-hour contact number(s): «Phone2»

You are being asked to take part in a clinical research study. However, before you agree to participate, you must understand the statements in this informed consent document. After that, please ask all the questions you want, especially to help you understand completely what will happen if you choose to participate in this study. You will be told of any important new information about the antibiotics used in this study which may effect your decision to participate.

Your doctor has diagnosed you with a skin infection. Skin infections happen when your skin is infected with germs called bacteria. Symptoms of a skin infection may include discharge ("pus") from the skin, warmth, pain, tenderness, redness, swelling, and/or fever. The standard treatment for many skin infections is antibiotic drugs. The antibiotics used to treat skin infections in this study must be given into a vein or administered as a shot into your buttocks. **Therefore, you should immediately inform the study doctor or staff if you have a history of allergies or other problems when taking any antibiotics or other medications.**

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Subject's Initials_____

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October 26, 2009

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People who are assigned to receive ceftaroline for the study will take part in pharmacokinetics (PK) study for ceftaroline. Pharmacokinetics can be defined as measuring how much study drug is absorbed and how much reaches the bloodstream and how it is broken down and removed from the body. This is important information in determining how the drug can be used safely with as few side effects as possible. Procedures for the PK study are done on Day 3 during drug treatment and consist of 5 blood draws.

Your doctor has decided that you must receive antibiotics by intramuscular injection or by vein to treat your skin infection. The antibiotics used to treat your skin infection in this study must be given by injection or into your vein for at least 5 days to 14 days. Typically you will begin treatment in the hospital or acute care facility. Your doctor may determine whether you finish your antibiotic treatment on an outpatient basis.

PURPOSE

The purpose of this clinical research study is to learn if an experimental antibiotic known as ceftaroline can safely and effectively treat the type of skin infection you have compared to another standard antibiotic. An “experimental” drug is one that has not been approved for sale by the U.S. Food and Drug Administration (FDA) and is being tested to see if it safely and effectively treats a disease or infection.

DESIGN

This is a randomized, open-label study. Randomization is a method based on chance by which you will receive either the experimental antibiotic or the standard antibiotic. In this study, there is a two to one chance that you will receive the experimental antibiotic rather than the standard antibiotic. In an open-label study, all participants receive treatment and no one receives a placebo. In this study approximately 100 people will be randomized to receive the experimental drug ceftaroline, and approximately 50 people will receive the standard antibiotic, Linezolid with possible aztreonam.

Approximately 150 people with a skin infection like yours will take part in this study at about 15 medical centers around the world. People who may take part are those who initially need to be in the hospital or acute care facility to receive antibiotic treatment for the skin infection. People who take part also must not have certain diseases, physical problems, or medical history that would prevent them from safely receiving the antibiotics used in this study. The study doctor and staff will ask you about your health and will do tests to decide whether you can take part in this study.

STUDY MEDICATIONS

If you qualify to participate in the study, you will receive either the experimental antibiotic ceftaroline, or the standard antibiotics, linezolid with possible aztreonam. Linezolid and aztreonam are standard antibiotics that are known to be able to treat most skin infections like yours. You are twice as likely to receive ceftaroline as you are to receive linezolid plus aztreonam. You will not receive a placebo for your skin infections. There are 2 groups in this study, and you will be provided with EITHER:

- **the experimental antibiotic ceftaroline by intramuscular injection (IM) OR**
- **The standard antibiotics linezolid with possible aztreonam injected directly into the vein (IV).**

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If you are accepted into the study, you will receive medication by injection every 12 hours or in your vein (IV) every 12 hours for 5 – 14 days. You will receive either ceftaroline at a dose of 600 mg by intramuscular (into the muscle) injection OR linezolid at a dose of 600 mg into your vein over 1 hour. If your doctor wants you to also receive aztreonam in addition to the linezolid, you will receive aztreonam 1000 mg by vein for one hour either with or immediately following the linezolid. Depending on the type of bacteria recovered from your infection, the aztreonam may be discontinued. Depending in how well your kidneys work, the dose of ceftaroline may be lowered.

DURATION

How long you are treated with the study antibiotics depends on how well the treatment works on your skin infection. The study doctor will decide how long you should be treated. You will be treated with antibiotics from 5 days to a maximum of 14 days. Your overall study participation will last about 26 to 49 days. You will be asked to return to the clinic a minimum of 9 times during this time period for study procedures.

STUDY PROCEDURES

After you have read this informed consent and agreed to take part in this research study, you will be asked to sign and date this form. The study staff will then do the following to decide if you can take part in the study:

- Ask you about your medical history, current and prior medicines, and current symptoms
- Perform a routine complete physical examination including taking your temperature, blood pressure, heart rate, breathing rate, and weight
- Perform a 12-lead electrocardiogram (also known as ECG), which is a painless test to check the electrical activity of the heart; this recording of your heart activity will be repeated 3 times
- Collect urine for a pregnancy test if you are a woman who is able to have children; if you are pregnant or nursing, you may **not** participate in this study and if you think you are pregnant, you must inform the study staff immediately
- Collect a urine sample for routine laboratory tests
- Collect blood samples (approximately 4 tablespoons) to determine if you can take part in the study and to check for the presence of bacteria in your blood; blood will be drawn from 2 separate veins
- Perform a complete examination of your skin infection, which will include taking a sample of tissue or fluid from the infection itself to check for bacteria; you doctor may also take a picture of the area of the infection
- Perform routine care of your skin infection to help healing of the infection

If all the testing indicates that you can take part in the study, the study antibiotics will be given by intramuscular injection (IM) or vein (IV) shortly thereafter. During the time you take the study antibiotics, your progress will be evaluated by tests like those used whenever a person needs antibiotics by vein. Some additional procedures will be done because this is a research study.

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Routine procedures while in the study:

- Ask you about any new symptoms (how you feel)
- Perform a routine brief physical examination including taking your temperature, blood pressure, heart rate, and breathing rate
- Collect urine samples for routine testing
- Perform a complete examination of your skin infection, which will include taking a sample of tissue or fluid from the infection itself to check for bacteria
- Perform routine care of your skin infection to help healing of the infection
- Collect blood samples (approximately 2 tablespoons) for routine testing. Blood samples (approximately 2 tablespoons) may also be collected to check for the presence of bacteria in your blood, if needed. Blood may be drawn from 2 separate veins for this test

Non-Routine procedures while on study:

- Perform several 12-lead electrocardiograms
- If you have a skin infection that is close to a bone, your doctor may perform an X-ray, MRI (magnetic resonance imaging) or CT scan (computed tomography), a painless test to see whether the bones were affected; if you have bone infection, you will not be able to participate in this study
- Females of child bearing potential will have an additional urine pregnancy test on the last day of antibiotic administration

If you receive the antibiotic ceftaroline, additional blood samples (5 blood samples of 1 tablespoon each) will be collected at each time point on Study Day 3.

- One sample immediately before the start of study drug intramuscular injection (IM)
- One sample between 5 minutes and 2 hours after the end of study drug intramuscular injection (IM)
- One sample between 2 and 4 hours after the end of study drug intramuscular injection (IM)
- One sample between 4 and 8 hours after the end of study drug intramuscular injection (IM)
- The last sample between 8 and 12 hours after the end of study drug intramuscular injection (IM)

For most people, it is expected that the antibiotics will be given by vein for 5 to 14 days. If the study doctor determines that the study antibiotics are not helping cure the infection, you will need additional drugs not allowed in this study. If this happens, the study antibiotics will be stopped.

Approximately 8 to 15 days after your last dose of the study antibiotics, you will be asked to return to see the study doctor for routine tests and an ECG. Approximately 21 to 35 days after your last dose of the study antibiotics, you will be asked to return for a last set of tests, including blood work and a review of the medications you are taking.

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RISKS AND DISCOMFORTS

Collection of Blood:

When blood samples are taken, you may have mild pain and/or bruising around the vein where the needle is inserted. Although rare, blood clots and infection of the vein may occur. Lightheadedness and/or fainting may also occur during or shortly after the blood is taken.

Antibiotics:

Most antibiotics, of any kind, may cause the following side effects: pain and swelling of the vein where the antibiotic is given, allergic reactions that can cause a sudden drop in blood pressure or difficulty breathing, skin rashes and sloughing of the skin, kidney damage possibly leading to kidney failure, low blood cell counts (which can be associated with infection, bleeding or fatigue), liver problems, seizures (fits), pseudomembranous colitis (a disease of the large intestine characterized by watery, sometimes bloody, diarrhea), and vaginal and mouth yeast infections (thrush). Some of these side effects can be severe, and on rare occasions they may cause death. Not all potential side effects are listed as some may be unknown at this time.

Ceftaroline (the drug being tested in this study):

Ceftaroline belongs to a group of antibiotics called cephalosporins. Like other cephalosporins, ceftaroline may cause certain side effects and discomforts. The most common known side effects and discomforts associated with ceftaroline are headache, microscopic crystals in urine, feeling sick to your stomach, creatine phosphokinase (an enzyme) increased in blood, difficulty sleeping, constipation, and abnormal liver tests. The most common side effects associated with ceftaroline when given by intramuscular injection (IM) include pain at the site of injection, diarrhea, feeling sick to your stomach, abnormal urine odor, headache, dizziness, itchiness, and rash. Since ceftaroline has been given to only a limited number of healthy people and people with skin infections, other side effects may be discovered, some of which could be severe.

Linezolid:

The most common side effects associated with linezolid are diarrhea, headache, feeling sick to your stomach, vomiting, trouble sleeping, constipation, rash, dizziness, and fever. In most cases these side effects are mild or moderate in severity. Colitis has been associated with nearly all antibiotics, including linezolid. Mild colitis usually stops when the drug is stopped. Other common side effects are described under the general antibiotics risks and discomforts section of this document.

Aztreonam:

The most common side effects associated with aztreonam include pain and swelling at the vein where the antibiotic is given, diarrhea, feeling sick to your stomach, vomiting, and rash. Severe side effects that may occur with aztreonam include rare, severe skin reactions.

REPRODUCTION RISKS

It is not known if ceftaroline is harmful to an unborn child or a nursing infant (effects on infants and pregnant women are unknown at this time). Therefore, women who are pregnant, nursing, or able to have children but not using a highly effective type of birth control may NOT take part in this study. Examples of highly effective birth control are use of a condom with spermicide, combined oral contraceptive (birth control pills), implant, injectable, intrauterine device (IUD),

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not having any sex (abstinence), or a vasectomized partner. All women who can have children must have a test that shows they are not pregnant before the study antibiotics are given. If you become pregnant while receiving treatment, you must inform your study doctor immediately and the pregnancy will be followed to outcome.

UNKNOWN AND UNFORESEEABLE RISKS/NEW FINDINGS

In addition to the risks and discomforts listed above, there may be some unknown or uncommon risks from the use of these study antibiotics. It may not be possible to predict some of these risks. You will be told by your doctor of any new information, findings or changes to the research that might change your wish to stay in this study. You will also receive this information in writing. You may contact the study doctor at any time after your participation ends to find out if any new information about this study has become available.

BENEFITS

You may benefit if the study antibiotics are able to cure your skin infection. It is possible that you may not personally benefit from being a part of this study. However, the study will provide additional information about the treatment of skin infections to physicians. Therefore, future patients may benefit from the increased knowledge of physicians who treat them.

ALTERNATIVES

You do not need to take part in this research study to get treatment for your skin infection. If you decide not to take part in this study, you will receive standard antibiotic(s) to treat infections like yours. There is no penalty or loss of benefit of other treatments if you do not participate. Ask the study doctor to tell you about these alternative treatments, including how they work.

COSTS

You will not have to pay for any of the study antibiotics, medical examinations, tests, hospitalization, or laboratory tests that are used only for purposes of this study. You may be required to pay for costs associated with what your physician would normally do to treat your skin infection.

COMPENSATION \$50 max per visit - \$450 max total

For your participation, you will be paid \$«MaxVisit».00 for each completed visit for a possible total of up to \$«MaxTotal».00. OR You will not receive any payment for taking part in this research study.

CONFIDENTIALITY AND RELEASE OF MEDICAL RECORDS

We will protect information about you and your taking part in this research study to the best of our ability. If information about this study is published, your name will not be given. However, the U.S. Food and Drug Administration (FDA), the Copernicus Group Independent Review Board (IRB), and «Company» may sometimes look at the medical records and study information of those who take part in this study. A court of law could order medical records shown to other people, but that is unlikely. Therefore, absolute confidentiality cannot be guaranteed.

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COMPENSATION FOR RESEARCH RELATED INJURY

If you are injured because of your taking part in this study, treatment for the injury will be made through «FirstName» «MiddleName» «LastName» «Suffix» and «Company».

The company responsible for this study will pay whatever costs of this treatment that are not paid by your medical insurance. There is no policy in place to provide additional compensation beyond the cost of treatment and no financial payment of any type will be provided by the company responsible for this study.

You must follow the directions of the study doctor to be eligible for this coverage.

LEGAL RIGHTS

You retain all legal rights while taking part in this study. You have the right to talk to a lawyer for advice and/or find other treatments if you are injured during the study.

VOLUNTARY PARTICIPATION

Taking part in this study is entirely voluntary (your choice). Your refusal to participate or your decision to discontinue your participation at any time will involve no penalty or loss of benefits to which you are otherwise entitled. If you stop taking part in the study, you may receive a standard treatment, and no prejudice or bias will be shown toward you for routine medical care. In addition, the study doctor or the company paying for this study may decide that you should no longer take part in the study. This may be done without your consent (agreement) if it is decided that you need additional treatment, do not follow the study plan, have a study-related injury, or for administrative reasons. If it is decided that you can no longer take part in the study, it is recommended that you finish the end of study examinations and laboratory tests.

WITHDRAWAL

Your doctor, the sponsor company, or the FDA has the right to stop your participation in the study at any time, with or without your consent, for any of the following reasons: if you have an adverse effect from the study drugs, if you need a treatment not allowed in this study, if you do not keep appointments, if you do not take the study drug as instructed, if you become pregnant, or if the study is canceled by the FDA or the sponsor company. The sponsor may decide to stop the study and your access to the study drug under certain circumstances even if the study drug appears to be safe and effective.

WHOM TO CONTACT FOR QUESTIONS

If you have any questions or problems during this study, or if you think that you may have had a research-related injury, you should contact:

«FirstName» «MiddleName» «LastName» «Suffix»
«Company»
«Address» «SuiteDept»
«City» «State» «Zip»
«Phone»

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If you have questions about your rights as a research subject, you may contact the Copernicus Group IRB at 1-888-303-2224 (toll free). An Independent Review Board is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the study subject's safety and welfare in mind. If you have study-related comments, complaints or concerns, you should first contact the study investigator. Please call the IRB if you want to talk to someone other than the study investigator or have difficulty reaching the study investigator. For further information regarding the clinical trials process and your role as a research subject, you may visit the Copernicus Group IRB website at www.cgirb.com.

SPONSORSHIP/FUNDING

The study doctor receives support payments from Cerexa, Inc., which is the company responsible for this study.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH

The United States government has issued a new privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization," describes your rights and explains how your health information will be used and disclosed (shared).

The information collected during this study will be kept confidential (private) to the extent permitted by the applicable laws and regulations. Only a study identification number and your initials will be used to identify you. You will not be personally identified (for example, mentioned by name) in any reports or publications that may result from this research study. Because of the research goals of this study, however, your study records cannot be kept completely confidential. Medical records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by authorized representatives of the following:

- The study personnel
- The sponsor and its agents and INC Research
- The FDA (the U.S. drug agency) and other regulatory agencies may review your medical records in order to review the study findings
- The Independent Review Board/Independent Ethics Committee (IRB/IEC)
- The hospital where you are being treated

The following sections provide a specific description of how your information will be used and disclosed (shared) if you take part in this research study. If you decide to take part in the study, you will be asked to authorize (legally agree to) those uses and disclosures by signing this form. If you choose not to authorize these uses and disclosures of your information, you will not be able to participate in the study.

The medical information that will be collected from you if you take part in the study includes (but is not limited to):

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- Information obtained from procedures to determine whether you can take part, including a routine medical history, physical examination, ECG, blood and urine tests, and urine pregnancy test.
- Information that is created, or collected from you, during the study, including all tests performed during the study.
- Information contained in your medical records related to your medical history, treatment, and hospitalization.

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, or other identifying information, as appropriate for the area in which you live.

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

- Cerexa, Inc.; INC Research; or other agents designated by Cerexa, Inc. (to collect or review study data)
- Copernicus Group IRB
- Government regulatory agencies, including the FDA and other governmental agencies in other countries

Once your information is disclosed to the study sponsors, the IRB, or government agencies as described above, it is possible that your medical information will be re-disclosed and will no longer be protected by U.S. federal privacy regulations. Other laws may provide further protection. Because of the need to disclose information to these parties, absolute confidentiality cannot be guaranteed.

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this Authorization you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

Your agreement to share the information from the study does not end when the study ends. In signing this form, you agree to the use and disclosure of your information for purposes of the study at any time in the future.

You may change your mind and decide to withdraw your approval to share this information at any time by sending a written request to:

«FirstName» «MiddleName» «LastName» «Suffix»
 «Company»
 «Address» «SuiteDept»
 «City» «State» «Zip»

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If you withdraw your approval, you will no longer take part in the study and no new information will be collected for study purposes unless the information concerns an adverse event (bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. If an adverse event occurs, your entire medical record may be reviewed. 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 study sponsor.

With the exception of adverse events, the study staff will stop using your information and will stop disclosing your information to the groups described above, except to the extent the study staff has depended on information that has already been collected from you. For example, the study staff may need to use or disclose information obtained before you withdrew your approval in order to preserve the scientific truth of the study.

If you withdraw from the study but do not withdraw your Authorization, new personal health information may be collected until this study ends.

This Authorization does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. ***will expire December 31, 2050. FOR WA sites*** Your study doctor will keep this Authorization for at least 6 years.

If you do not sign this Authorization, you cannot participate in this research study or receive study-related treatment. If you withdraw this Authorization in the future, you will no longer be able to participate in this study. Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of a signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Signature of Subject

Date

Approved «Approved»**SUBJECT'S STATEMENT OF CONSENT AND AUTHORIZATION**

I have read the statements in this informed consent. I have been able to ask any and all questions, and I am satisfied with the answers provided. I agree of my free will to take part in the study, and I agree to the use and disclosure of my information in connection with the study. I understand that I (or my legally acceptable representative) will receive a signed copy of this consent and authorization form.

Signature of Subject

Date (personally by Subject)

Printed name of Subject

Signature of Person conducting the
Informed Consent Discussion

Date (personally by Person conducting the
Informed Consent Discussion)

Printed name of Person conducting Informed Consent Discussion