

Cerexa, Inc.
Ceftaroline for Injection

Informed Consent for Protocols P903-06, P903-07
FINAL Draft of 22 September 2006

**CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION**

Sponsor: Cerexa, Inc.

Study Title: A Phase 3, Multi-Center, Randomized, Double-Blind, Comparative Study to Evaluate the Safety and Efficacy of Ceftaroline Versus Vancomycin plus Aztreonam in Adult Subjects with Complicated Skin and Skin Structure Infections

Protocol Number: [P903-06] [P903-07]

Investigator:

Address:

Telephone Number:

You are being asked to take part in a clinical research study. However, before you agree to take part, 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 take part in this study. You will be told of any important new information about the antibiotics used in this study which could change your decision to take part in this study.

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. ***Therefore, you should immediately inform the study doctor or staff if you have a history of allergies or problems when taking any antibiotics.*** Your doctor has decided that you must stay in the hospital for several days to receive antibiotics by vein to treat your infection. The antibiotics used to treat skin infections in this study must be given into your vein.

PURPOSE

The purpose of this clinical research study is to learn if an investigational antibiotic known as ceftaroline can safely and effectively treat skin infections, compared to standard antibiotics. An "investigational" drug is one that has not been approved for sale by the U.S. Food and Drug Administration (FDA) [or your national health/regulatory agency] and is being tested to see if it safely and effectively treats a disease or infection.

DESIGN

This is a randomized, double-blind study. Randomization is a method based on chance by which you will receive either the investigational antibiotic or the standard antibiotics. In this study, there is an equal chance that you will receive the investigational antibiotic or the standard antibiotics. In a double-blinded study, neither you nor your study doctor or study staff know

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which antibiotic you are receiving. Not knowing your antibiotic will help your doctor treat you and other people in the study in the same way.

Approximately 550 people with infections like yours will take part in this study at about 75 to 80 medical centers around the world. People who may take part are those who initially need to be in the hospital and to receive antibiotic treatment by vein for their 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 are accepted into the study, you will receive either the investigational antibiotic ceftaroline plus placebo or the standard antibiotics, vancomycin plus aztreonam. The placebo is a liquid that cannot cure your skin infection and usually has no side effects. The addition of placebo is to ensure that neither you nor your study doctor knows which treatment group you are in. Vancomycin and aztreonam are standard antibiotics which are known to be able to treat most skin infections like yours. You are just as likely to receive ceftaroline plus placebo as you are to receive vancomycin plus aztreonam. You will not receive only the placebo as a treatment for your skin infection.

You will receive your antibiotic every 12 hours. You will receive EITHER ceftaroline at a dose of 600 mg into your vein over 1 hour, immediately followed by placebo for 1 hour, OR vancomycin at a dose of 1000 mg into your vein over 1 hour, immediately followed by aztreonam 1000 mg by vein for 1 hour. Depending on how well your kidneys work, the dose of ceftaroline or vancomycin may be lowered.

DURATION

How long you are treated with the study antibiotics depends on how you feel during treatment and how well the treatment works on your skin infection. The study doctor will decide how long you should be treated. The expected number of days you will receive study antibiotics is from 5 days up to a maximum of 21 days. Your overall study participation will last about 26 to 56 days.

STUDY PROCEDURES

After you or your legally authorized representative have understood 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 complete physical examination including taking your temperature, blood pressure, heart rate, breathing rate, and weight.
- 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 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.

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- If you are a woman who is able to have children, urine will be collected for a pregnancy test. If you are pregnant, you may **not** participate in this study. 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 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 vein 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 tests will be done because this is a research study.

Routine procedures while on treatment:

- Ask you about any new symptoms (how you feel).
- Perform a brief physical examination including taking your temperature, blood pressure, heart rate, and breathing rate.
- Examine the infected area of your skin. This may include taking a sample of tissue or fluid from the infected site to check for the presence of bacteria.
- Collect urine samples for routine testing.
- 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.
- Perform routine care of your skin infection to help healing of the infection.

Non-Routine procedures while on therapy

- Perform several 12-lead electrocardiograms.

For most people, it is expected that the antibiotics will be given by vein for 5 to 14 days. However, in unusual cases up to 21 days of treatment may be needed. 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. At the end of treatment, routine tests will be done to see if your infection has improved or gone away completely. 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. Approximately 21 to 35 days after your last dose of the study antibiotics you will be asked to return to for a last set of evaluations. The person deciding how the antibiotics are treating your infection will not know which antibiotics you have received.

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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 or bleeding), 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.

Ceftaroline:

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) increase in blood, difficulty sleeping, constipation, and abnormal liver tests. Since ceftaroline has been given to only a limited number of healthy people, and people with infections like yours, other side effects may be discovered; some of these could be severe.

Vancomycin:

The most common side effects associated with vancomycin include chills, fever, feeling sick to your stomach, ringing in the ears, hives, skin rash, and redness, swelling or pain of the vein where the antibiotic is given. A flushing of the head and neck may occur if vancomycin is given into the vein too quickly. Severe side effects that may happen with vancomycin include decreases in some blood cell counts, making you more prone to bleeding or infection. In addition, vancomycin may damage the kidney, possibly leading to kidney failure, and/or damage the nerves of the ear, which may lead to hearing loss or dizziness.

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.

PREGNANCY

Ceftaroline might hurt 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 or without spermicide, combined oral contraceptive (birth control pills), implant, injectable, intrauterine device (IUD), 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.

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UNKNOWN AND UNFORESEEABLE RISKS

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.

BENEFITS

You may benefit if the study antibiotics are able to cure your skin infection. It is also possible that you may not personally benefit from being a part of this study. However, this 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. 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 required only for you to take part in this study.

COMPENSATION

You will not be paid for taking part in this study.

IN CASE OF INJURY

If you are injured because of your taking part in this study, treatment for the injury will be made through

[name of physician]

and

[this institution].

The company responsible for this study will pay whatever costs of this treatment are not paid by your medical insurance. No other money or financial payment of any type will be provided by the company responsible for this study. 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.

WHOM TO CONTACT

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:

[investigator name]

[address].

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[telephone number].

If you have any questions regarding your rights as a research volunteer, please contact during regular working hours:

[insert name],

Chairman of the Institutional Review Board/Independent Ethics Committee (IRB/IEC)

[insert telephone number(s)].

The Institutional Review Board/Independent Ethics Committee (IRB/IEC) is a committee established for the purpose of protecting the rights of volunteers in a research 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.

SPONSORSHIP/FUNDING

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

CONFIDENTIALITY AND AUTHORIZATION TO ACCESS AND USE MEDICAL INFORMATION

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 [insert CRO name]
- The FDA (the U.S. drug agency) and other regulatory agencies may review your medical records in order to review the study findings
- The Institutional Review Board/Independent Ethics Committee (IRB/IEC))
- The hospital where you are being treated

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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 take part 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):

- 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 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, 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., [insert CRO name] or other agents designated by Cerexa, Inc., to collect or review study data.
- The IRB/IEC
- Government regulatory agencies including the FDA and other governmental agencies in other countries.

Once your information is disclosed to the study sponsors, the IRB/IEC, 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.

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:

[insert name of responsible study personnel]

[insert address].

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If you withdraw your approval, you will no longer take part in the study and the study staff will stop collecting medical information from you. In addition, 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.

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SUBJECT'S STATEMENT OF CONSENT AND AUTHORIZATION

I have read and understand 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

I certify that under local law I am the legally authorized representative of the participant named above and that I am authorized to sign this consent to his/her participation in the medical research study described above. I also am authorized to sign this authorization to release medical records and health information as described above.

Signature of Legal Representative

Date

Printed name of Legal Representative