Please check one of the following:

_____ You are an adult subject in this study.

_____ You are the parent or guardian granting consent for a minor in this study.

Print minor's name here:

_____

The following information applies to the individual or to his/her minor child. If the subject is a minor, use of "you" refers to "your child".

Are you participating in any other research studies? _____ yes _____ no

Introduction to Research Studies

A research study is designed to answer specific questions, sometimes about a drug or device's safety and its effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your personal doctor have a great deal of freedom in making decisions about your health care. When you are a research subject, the Protocol Director and the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

Purpose of Research

You are invited to participate in a study to evaluate OMS103HP (an investigational medicine). We hope to learn whether treatment with OMS103HP will result in early improvement in knee pain and knee function. We also will evaluate the safety of OMS103HP. You were selected as a possible participant in this study because you are scheduled to undergo surgical reconstruction of your anterior cruciate ligament (a major ligament inside your knee) using an allograft (a ligament from a cadaver). Your participation in this study is entirely voluntary. Approximately 280 subjects throughout the United States will participate in this study. Stanford University expects to enroll approximately 50 research study subjects.

Duration of Study Involvement

This research study is expected to take approximately 3 to 3½ months. This includes a Screening visit up to 14 days before the day of your knee surgery followed by 30 days of active participation. The final visit will be 90 days after the surgical procedure.

Procedures

If you decide to participate, the Protocol Director or an associate will explain the study procedures to you. Your participation in this study will involve Screening and Baseline evaluations to determine whether you will qualify for the study. The Screening evaluation will occur up to 14 days before the day of your knee surgery, and the Baseline evaluation will occur within 24 hours of your surgery. You will be required to return to the clinic for seven visits after the surgery, and these clinic visits will occur 1, 3, 6, 10, 20, 30 and 90 days after your surgery. Every attempt will be made to have these visits correspond to the standard postoperative visits. You will also be required to participate in the standard study rehabilitation program. Your Screening and Baseline evaluations will take place at the Sports, Orthopedic and Rehabilitation Medicine Associates (S.O.A.R.) facility and at Stanford University Hospital. Your surgery will take place at Stanford University Hospital or Waverley Surgical Center. Your outpatient clinic visits will take place at S.O.A.R. Your rehabilitation visits will take place at a rehabilitation facility approved for this study.

During the Screening visit, a medical and surgical history will be taken. Also, a general physical examination, a knee examination and an anesthesia evaluation will be performed. Approximately two tablespoons of blood will be taken from a vein in your arm with a needle for clinical laboratory evaluations. If you have not had an x-ray of your knee within 6 months, an x-ray will be taken. A urine sample will be taken for a pregnancy test (women only) and a urine drug screen. Results of the urine drug screen will remain confidential and will not be included in your Stanford medical record nor will they be made available to your insurance carrier. The responses to questions concerning illegal drug use could be self-incriminating and harmful to you if they became known outside the study. As explained in the confidentiality statement on page 7 of the consent, we do not intend to disclose this information. If the drug screen was positive for an illicit drug and was subpoenaed or somehow disclosed, an unlikely event, it could be incriminating. Blood or tissue samples will be destroyed when the study is complete. Also during Screening, you will be instructed on how to perform daily home exercise and icing of your knee.

At the Baseline visit, results of the Screening evaluation will be reviewed and your eligibility for this study confirmed. In addition, evaluations of your knee pain and function will be performed. If you are accepted into this study, on the day of arthroscopic knee surgery, you will be assigned by chance to the group receiving OMS103HP solution or to the group receiving standard solution. You will have a fifty percent chance of receiving the study drug. Neither you, your surgeon nor any member of the research staff will know which treatment you will receive in this study. Your surgery will be performed according to your surgeon's usual surgical procedures, with the exception that the solution that is flushed through your knee during surgery will either contain OMS103HP or will be the standard solution without anything added to it.

After the knee surgery, you will be given a prescription for a narcotic pain medication to use when you return home. You can only take the prescribed pain medication during this study. Other pain or anti-inflammatory medications might interfere with the study evaluations and are not allowed. If you have a problem with the prescribed pain medication you should contact your surgeon. You also will be given a diary and asked to record the number of pain pills that you take each day during the first 30 days of the study as well as whether you returned to work. You will be given instructions for icing your knee each evening.

You will be required to return to the clinic 1, 3, 6, 10, 20, 30 and 90 days after your knee surgery. Each visit will be approximately 1 hour, with the last two clinic visits taking approximately 1½ hours. At all of the clinic visits after your surgery, your knee will be examined and you will be interviewed about side effects that you may have experienced. At the Day 10 clinic visit, approximately two tablespoons of blood will be taken from a vein in your arm with a needle for clinical laboratory evaluations. A general physical examination also will be performed at the Day 10 clinic visit. A knee examination will be performed at the Day 30 and Day 90 clinic visits.

During the first 30 days after your knee surgery, you will participate in the standard study rehabilitation program. This involves performing daily home exercises, icing of your knee and returning to the rehabilitation facility approximately three times a week for 12 visits during this 30-day period (in addition to the clinic visits already mentioned).

Women of Childbearing Potential

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

To confirm to the extent medically possible that you are not pregnant, you agree to have a pregnancy test done before beginning this research study. You must agree to use a birth control method judged to be effective by the Protocol Director and which will not interfere with the study. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the Protocol Director or his associates as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

Subject's Responsibilities

You should:

- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Keep your diaries as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.
- You will have to sign this consent and Authorization form if you want to participate in this research study.

While participating in this study, you should not take part in any other research project without approval from the Protocol Director. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, interaction of research drugs, or similar hazards.

Withdrawal from the Study

Your decision whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are free to withdraw your consent including your authorization regarding the use and disclosure of your health information, and to discontinue participation at any time without prejudice to you or effect on your medical care. If you wish to participate in this study, you must sign this form. If you decide to terminate your participation in this study, you should notify Dr. Michael Dillingham at (650) 851-4900.

At the discretion of the Protocol Director, subjects may be taken out of this study without their consent. Some possible reasons for withdrawing a subject from the study:

- failure to follow instructions

- the Protocol Director decides that continuation could be harmful to you
- you need treatment not allowed in the study
- pregnancy
- the study is canceled
- other administrative reason(s)
- unanticipated circumstances

If you withdraw from the study before completing all evaluations, you will have to participate in a final clinic visit. The procedures performed at this visit may include a general physical examination, a knee examination, and obtaining approximately two tablespoons of blood from a vein in your arm with a needle for clinical laboratory evaluations.

Possible Risks, Discomforts, and Inconveniences

The potential risks associated with the uses of the test solutions are:

1. You may experience an allergic reaction to one of the active ingredients in OMS103HP. The Protocol Director or his associates will screen all subjects before the study for a history of allergic reactions to any of the active ingredients in OMS103HP or similar classes of drugs.

2. You may receive the standard solution rather than the OMS103HP solution, or if you do receive the OMS103HP solution, you may not experience early improvement in knee pain and knee function. To minimize your discomfort, you will be given standard pain medications in the recovery room and following the surgery, as prescribed by the surgeon.

3. Although OMS103HP is being flushed through your knee joint during knee surgery, small amounts may temporarily circulate in your blood stream.

4. Minor local reactions to OMS103HP around the area of knee surgery rarely may occur.

5. The procedure for taking blood may cause you to experience local discomfort, bruising, swelling and in rare cases, a local infection.

6. Because OMS103HP is an investigational drug, risks that are unknown at this time may occur.

Potential Benefits

Potential benefits include (1) early improvement in the function of the knee, (2) decreased use of pain medications in the postoperative period, (3) early improvement in knee motion and (4) earlier return to work. In addition, the information obtained in this study will be used to obtain FDA approval to market OMS103HP. WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

You will be told if any new information is learned which may affect your condition or influence your willingness to continue participation in this study.

Alternatives

If you elect not to participate in the study, the standard solution that is usually used in arthroscopic surgery will be flushed through your knee joint during your surgery. There are no alternative therapies that can be added to the solution flushed through the knee during arthroscopic surgery. The Cryo/Cuff™, Polar Care™ or other cooling devices, which sometimes are applied postoperatively as a cold pack, will not be used in this study due to potential interference with study evaluations. You will be given instructions for icing your knee, and you will have the option of using a cold pack for swelling, postoperatively.

Subject's Rights

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

If you decide not to participate, tell the Protocol Director. You will still receive care for your disease and will not lose any benefits to which you would otherwise be entitled.

As a human subject you have the following rights. These rights include but are not limited to the subject's right to:

- be informed of the nature and purpose of the experiment
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized
- be given a description of any attendant discomforts and risks reasonably to be

expected

- be given an explanation of any benefits to the subject reasonably to be expected, if applicable
- be given a disclosure of any appropriate alternatives, drugs, or devices that might be advantageous to the subject, their relative risks and benefits
- be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise
- be given an opportunity to ask questions concerning the experiment or the procedures involved
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice
- be given a copy of the signed and dated consent form; and 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

Confidentiality

Any data that may be published in scientific journals will not reveal your identity. Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique subject number. Information about the subject number will be kept in a secure location and access will be limited to research study personnel. Subject information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction. Officials of the FDA, Omeros Corporation (the sponsor of the study), and the Protocol Director and his associates who are participating in this study may inspect all records (including your medical records) from this study due to their support and interest in this study. Records will be used by the FDA, Omeros, and the Protocol Director only in connection with carrying out their obligations relating to this study, and every effort will be made to keep the records as confidential as possible, within the limits of the law. Additionally, if required, the Stanford University Administrative Panel on Human Subjects in Medical Research may inspect all research records.

General Information for Studies under the Jurisdiction of the FDA

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this research is to obtain data or information on the safety and effectiveness of OMS103HP; the results will be provided to the sponsor, the Food and Drug Administration and other federal agencies as required.

By signing this form, you are authorizing the use and disclosure of your health information collected in connection with your participation in this research study. Your information will only be used in accordance with the provisions of this consent form and applicable law. If you decide to terminate your participation in the study, or if you are removed from the study by the Protocol Director, you may revoke your authorization, except to the extent that the law allows us to continue using your information.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to

discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must contact: *Dr. Dillingham at (650) 851-4900.*

What Personal Information Will Be Used or Disclosed?

Your health information related to this study, including, but not limited to, information that exists prior to participation in a research study (e.g., medical records, demographic information, laboratory test results, etc.) and information that is generated as part of participation in the research study (e.g., clinic and rehabilitation chart notes, etc.) may be used or disclosed in connection with this research study.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director: Dr. Dillingham
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary.
- The research team including sub-investigators, study coordinators, study anesthesiologists, study nurse practitioners, pharmacists and your rehabilitation provider.

Who May Receive / Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Omeros Corporation (the sponsor) and its designees
- Federal and state regulatory agencies (e.g. Food and Drug Administration and other agencies as applicable) and other domestic or foreign regulatory bodies
- Other institutions and research sites participating in the multicenter research study

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will expire on 09/28/2054. If subjects wish to withdraw their authorization, you may do so at any time by notifying the Protocol Director in writing. However, withdrawal of authorization is not retroactive and the Protocol Director is not required to destroy or retrieve protected health information that has already been used or disclosed prior to notification of withdrawal of authorization.

Will access to my medical record be limited during the study?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make medical or billing decision about you (e.g., if included in your official medical record).

(If consent is to be obtained from a legally authorized representative (e.g., parent(s), legal guardian or conservator), signature line(s) for representative must be included on the consent form, as well as a description of his/her authority to act for the subject.)

_____

Signature of Subject

_____

Signature of Legally Authorized Representative

_____

Date

_____

_____

Description of Representative's Authority to Act for Subject

Payment

Subjects will be paid a maximum of $500 for participation in this study. Subjects will be paid $60 for each of the first five outpatient clinic visits (Day 1, 3, 6, 10 and 20) and $100 for the each of the clinic visits at Day 30 and Day 90. Payments will be paid after each visit. If you withdraw from the study before completion, you will be paid for each completed study visit. Legally, you can be paid only if you are a U.S. citizen, a legal resident alien (i.e., possess a "green" card), or have a work eligible visa sponsored by the paying institution.

Sponsor

Omeros Corporation is providing financial support for this study. Omeros will supply OMS103HP and will pay for the urine pregnancy test, urine drug screen and Screening and final blood draws for clinical laboratory evaluations.

Costs

You or your insurance company will be responsible for all other costs routine to your type of operation.

Contact Information

Appointment Contact: If you need to change your appointment, please contact Dr. Dillingham or his associates at (650) 851-4900.

Questions, Concerns, or Complaints: *If you have any questions, concerns or complaints about this **research study**, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director. You may contact Dr. Dillingham or his associates at (650) 851-4900

Emergency Contact: *If you feel you have been **hurt by being a part of this study**, or need immediate assistance please contact Dr. Dillingham or his associates at (650) 851-4900.

Independent of the Research Team Contact: *If you are not satisfied with the manner in which this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a research study subject, please contact the Stanford Institutional Review Board (IRB) to speak to an informed individual who is independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. Or write the Stanford IRB, Administrative Panels Office, Stanford University, Stanford, CA 94305-5401. In addition, please call the Stanford IRB at either (650)-723-5244 or toll free at 1-866-680-2906 if you wish to speak to someone other than the research team or if you cannot reach the research team.

Compensation

All forms of medical diagnosis and treatment - whether routine or experimental - involve some risk of injury. Despite all precautions, you might develop medical complications from participating in this study. If such complications arise, the researchers will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for additional medical or other costs. You do not waive any liability rights for personal injury by signing this form.

Consent

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

_____ _____
Signature of Subject Date

_____
Subject's Social Security Number

Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the subject has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

_____ _____
Signature of Person Obtaining Consent Date