Frequently Asked Questions

What is the nature of this study?

This study is a Phase I/II trial of a treatment for **advanced prostate cancer** that involves the freezing ("cryoablation") of a known cancer in the prostate followed by the injection of dendritic cells into the frozen area of the prostate.

> "Phase I/II trial" means that this clinical trial (study) is designed to investigate both the safety and the effectiveness of the study treatment. It also means that this study is investigational, and that the treatment has not been approved by the U.S. Food and Drug Administration (FDA). This study will provide evidence to the study investigators and others regarding whether or not the study treatment should be studied further.
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> The cryoablation part of the study treatment is intended to "kill" the cancer that is relatively easy to get access to. In this study, the cancer to be cryoablated is the cancer in the prostate. In order to get the study treatment, your doctors will need to know that there is in fact cancer in your prostate. This is usually determined by a biopsy.
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> The dendritic cell component of this study involves the injection of millions of dendritic cells into the cancer that has been "killed" by the freezing. The dendritic cell is a specific kind of immune cell that is capable of capturing material (antigen) from the frozen cancer and causing an immune response against related cancers elsewhere in the body.

This study also involves that each study patient take a low dose of a chemotherapy drug (tablet) called "cyclophosphamide" for a six month duration.

This study will enroll approximately 26 men who have androgen independent (also known as "hormone refractory"), metastatic prostate cancer.

How will I know if I qualify for this study?

You will need to contact the office of one of the study physicians (doctors):

Duke Bahn, M.D. Prostate Institute of America, Ventura, California 888-234-0004
Mark Scholz, M.D. Prostate Oncology Specialists, Marina del Rey, California 310-827-7707

You will need to supply information about your case, including recent medical records and laboratory results, to one of the study doctors. You will likely speak on the telephone to one of the study doctors' representatives (study coordinator or nurse) in order to determine your eligibility for the trial.

What are the eligibility requirements for the trial?

A full list of the eligibility criteria (referred to as Inclusion and Exclusion Criteria) is available on the internet at: http://www.clinicaltrials.gov/ct2/show/NCT00753220?term=NCT00753220&rank=1

In short, a patient eligible for entry into this trial will have cancer both in his prostate and in the form of cancer metastases outside the prostate. However, there must only be three or less metastases as determined by the study doctors. The cancer must also be androgen independent (hormone refractory), which means that hormonal treatments have stopped working. Lastly, no chemotherapy must have been undertaken to treat the prostate cancer.

Many of the other criteria are related to laboratory tests and other studies that may have already been completed by your own doctor(s). If you are not familiar with the results of these tests, you may want to request that a copy of your records be sent to one of the study doctors after speaking with a study doctor's office. This process is also known as the "screening" process.

IMPORTANT: PLEASE DO NOT SEND MEDICAL RECORDS BEFORE SPEAKING WITH ONE OF THE STUDY DOCTORS OR HIS STAFF AT THE NUMBERS ABOVE.

How do I get enrolled to the study?

Your records will need to be reviewed by one of the study investigators (doctors), Dr. Duke Bahn or Dr. Mark Scholz. If one of these doctors finds that you meet the study eligibility criteria, you will be asked to review the informed consent (IC) document. The IC will tell you everything that you need to know about the study treatment, and it is important that you review it carefully.

Once you have reviewed the IC, and it appears that you are eligible for the study, you will need to arrange for an appointment at a study doctor's office. You may need to have further tests performed, such as blood tests, bone scan, and/or CT scan.

If you are determined at that time to qualify for the study, you will be "enrolled to the trial", and the scheduling of the study treatment will begin.

What does the study treatment involve?

Once you are enrolled to the study, the preparation of the dendritic cell component of the treatment will begin. You will be flown to Seattle, Washington, where – the following morning -- you will undergo a "leukapheresis" (loo-ka-fer-EE-sis"). For this procedure you will have needles placed into your arm veins, as if you were to have a blood draw. Unlike a blood draw, however, you will stay connected to a piece of equipment for about four hours. You will then be free to fly back home.

The leukapheresis product obtained from you will be used to prepare the dendritic cell part of the treatment, known as "VDC2008". You will be arranged for a cryoablation of the prostate procedure at the Prostate Institute of America by Dr. Duke Bahn. The VDC2008 cells will be sent from Seattle to Dr. Bahn's office for the injection into your prostate following cryoablation. Three days before the cryoablation procedure, you will receive a low dose of the chemotherapy drug cyclophosphamide intravenously (IV).

After the study treatment, you will spend overnight in the hospital, and will then be discharged to go home.

What else does the study involve?

Following the study treatment, you will need to visit one of the study doctors (Dr. Bahn or Scholz) several times over the course of the next year.
You will also be prescribed a regimen of the chemotherapy drug cyclophosphamide, which you will take by mouth for six months after the study treatment. You will be asked to fill out a calendar that indicates when you take each dose (one tablet per dose).

You will also need to stay in touch with the Study Coordinators (Lisa Valdes, RN and Dana Vaughan), and keep these individuals apprised of anything that occurs related to your prostate cancer or the study treatment.

At six months and one year following the study treatment, you will under a bone scan and computed tomography (CT) examination as part of the study. As with all parts of the study treatment and follow-up, there will be no cost to you. However, you will be responsible for transportation to and from your treatment visit (Community Memorial Hospital, Ventura, California) and study doctor follow-up visits, with the exception of the trip to Seattle for leukapheresis, which will be arranged for you.