Us TOO PROSTATE CANCER EDUCATION & SUPPORT
HOTSHEET

SPECIAL BURNING ISSUES SUPPLEMENT
OCTOBER 2006

THIS SUPPLEMENT TO THE *US TOO PROSTATE CANCER HOT SHEET* WAS MADE POSSIBLE BY A CHARITABLE CONTRIBUTION FROM

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CLINICAL TRIALS FOR ADVANCED PROSTATE CANCER

INTRODUCTION BY THOMAS N. KIRK PRESIDENT & CEO

Welcome to the inaugural issue of the special *HotSheet Burning Issues Supplement!* We often receive questions and comments on a number of prostate cancer-related topics, and try to cover them in each issue of our *HotSheet*. But we have received enough questions and feedback about advanced prostate cancer patient concerns and what clinical trials are available, that we have decided to create a special supplement to the *HotSheet* to expand on these topics more for you.

In a 2005 survey of more than 400 advanced prostate cancer patients, Us TOO learned that, overall, advanced prostate patients are largely dissatisfied (63 percent) with the treatment options available to them today. If their prostate cancer should progress, patients and caregivers who responded to the survey told us that their top three choices for treatment are experimental drugs obtained though a clinical trial (60 percent), hormone therapy (57 percent), and chemotherapy (53 percent).

In this issue, you will find articles on how one biopharmaceutical company became involved in developing a new treatment for advanced prostate cancer, how one advanced disease patient got involved in a clinical trial, and learn more about selected clinical trials currently enrolling for advanced/metastatic prostate cancer.

We are considering producing a *HotSheet Burning Issues Supplement* on a quarterly basis if the interest is there. Please forward your suggestions for future supplement topics to me at <tom@ustoo.org> or call 630-795-1002 and let me know if you find the information presented here useful.

Thomas N. Kirk, President & CEO, Us TOO International

PATIENT STORY: GIVE IT ALL YOU GOT

As a commander in the Army's elite Special Forces who served in Vietnam and Desert Storm, Jim Torpey is not easily intimidated. Cross-trained as a Special Forces medic, Jim is a volunteer emergency medical technician and firefighter. Jim's courage, steely determination and zest for life are most evident, however, when he recounts his battle with prostate cancer.

At just 50, Jim was diagnosed with prostate cancer. Shocked and frightened, he felt terribly overwhelmed with deciding how to fight this new enemy. While physicians inform patients of their options, the onus of selecting a treatment course often rests with the patient – a daunting responsibility, even for someone with medical experience, like Jim.

Jim decided he could either be a fatalist or a realist. With his wife Marcy's support, he set aside his fear and got to work. Jim became his own advocate, conducting research, asking questions, and weighing his options. He realized that he would have to take some leaps of faith and assume calculated risks with his life in the balance.

In 2000, Jim had his prostate removed. Two years later, a marked increase in his PSA level prompted

Photograph by Lucille Anne Newman

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Insight Into How a Company Gets Involved in Developing A New Treatment for Advanced Prostate Cancer

Recently we had a chance to speak with John G. Curd, MD, president and chief medical officer of Novacea, a biopharmaceutical company.

Why cancer for Novacea? Why prostate?

Novacea was founded on a novel technology developed by Drs. Tomasz Beer and David Henner at Oregon Health & Science University (OHSU). We believed in their technology, knew there was a huge unmet medical need in advanced prostate cancer, and felt that it could be moved into the clinic very quickly – so we formed a company to develop this treatment.

What is Asentar™, more commonly known as DN-101?

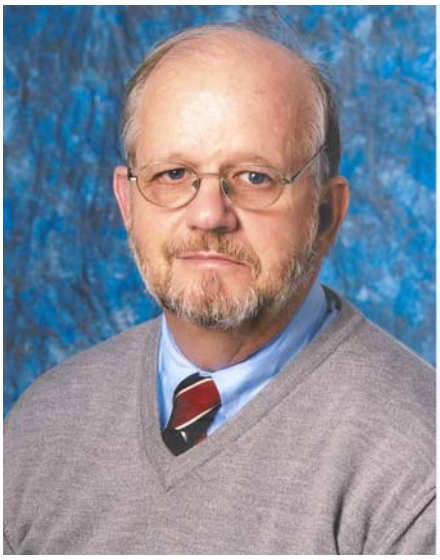
Asentar is a high-dose oral formulation of calcitriol, a biologically active form of vitamin D and a naturally occurring hormone. When Drs. Tomasz Beer and David Henner first proposed using mega doses of vitamin D to fight advanced prostate cancer, most of the scientific community thought they were – at best – misguided.

Despite volumes of scientific data that confirmed calcitriol's anti-tumor activity, at those high levels it could not be administered to patients without causing severe toxicity, in particular hypercalcemia (an abnormally high concentration of calcium in the blood).

However, they persevered and were able to overcome this obstacle. Through a series of studies, they discovered that administering calcitriol before chemotherapy could yield very encouraging results.

What did Novacea learn from its clinical trials?

A Phase 1 safety study was successfully completed in 2002 which allowed us to initiate ASCENT, a 250-patient Phase 2 trial, which was unusually rigorous. All patients received Taxotere weekly, but half of the group received Asentar the day before chemotherapy treatment. Based on the encouraging survival benefit without the limiting toxicities in a large randomized trial, we are currently conducting a 900-patient Phase 3 trial to confirm these findings and to seek FDA approval.



What does it mean to you when an investigational drug demonstrates success?

There are so many elements needed to get a drug through clinical trials and to the patients, including researchers, doctors and patients themselves – that I am always elated when I see very encouraging results like we saw in ASCENT.

Give It All You Got

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radiation treatment and hormone therapy. Jim persevered with treatment for two years, despite side effects of his disease and treatment, like a softening of his muscular physique and incontinence.

A bone scan conducted in September 2005 revealed that Jim's cancer had started to metastasize, or spread to his bones. He started treatment to rebuild some of the bone mass lost to radiation, but by the following spring the cancer had metastasized significantly. Chemotherapy was the next step.

When Jim first became a patient at the Cancer Center of Cape Fear Valley Medical Center, he had expressed a willingness to consider enrollment in clinical studies. Now, after discussing this option with his doctor, he decided to enroll in an advanced prostate cancer study known as ASCENT-2.

Jim opted to join the study for a few reasons. He hoped that it might benefit him; however, if it did not, he felt it might benefit someone down the road – perhaps even one of his own sons. He also would not have to travel to participate, allowing him to work and to be near family and friends. He also felt fully informed about the risks and benefits of participating in the study.

Since beginning the study, Jim has responded well to chemotherapy and may be able to stop treatments in December if his progress continues. In the meantime, he takes advantage of monthly massage therapy to help him reduce anxiety before chemotherapy sessions, and he handles the side effects with optimism and a sense of humor, joking - "Wouldn't it be cool if I became a flaming redhead when my hair grows back?"

In the midst of his treatments, Jim has found the time and energy to co-facilitate a local support group for prostate cancer patients. He also serves as a resource for newly diagnosed patients, offering support, information and advice.

Cancer is an intimidating enemy. But for this proud grandfather of four little girls, "giving it all you got" is the only option.

How To Search for a Clinical Trial

Clinical trials (also called clinical studies) are an important treatment option for you to understand and consider as you manage your cancer. A clinical trial is a research study to answer specific questions about vaccines, new therapies, or new ways of using known treatments. They determine whether new drugs or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people.

Information on federally and privately supported clinical trials for a wide range of diseases and conditions being conducted in all 50 states and in over 130 countries is available to the public at a federally sponsored, free web site – www.clinicaltrials.gov. Here you can find a comprehensive listing of over 360 clinical studies for various stages and types of prostate cancer and related issues (e.g., bone metastases, fatigue, urinary incontinence, etc.).

To learn how to best utilize and navigate www.ClinicalTrials.gov, you may want to first familiarize yourself with the web site by starting at Resource Information. This section reviews information that explains and describes clinical trials and common terms associated with these studies.

When you are ready to search for clinical studies, you can begin with a general search or a more focused one. Search terms you can use include disease, trial location, age, study phase, or other descriptive words.

For example, if you wanted to learn about Phase III clinical trials for metastatic prostate cancer that is hormone refractory or androgen independent, you would begin your search with prostate cancer, then metastatic, then Phase III – refining the search with each new term. You should find the following studies:

Provenge® Immunotherapy Vaccine for the Treatment of Metastatic Prostate Cancer After Failing Hormone Therapy

Provenge (sipuleucel-T) is an investigational product that may represent the first in a new class of active cellular immunotherapies (ACIs) that are uniquely designed to stimulate a patient's own immune system. Provenge is in clinical development for the treatment of patients with early and advanced-stage prostate cancer. Two important Phase 3 trials of Provenge have been completed; the current trial, also called IMPACT (IMmunotherapy for Prostate AdenoCarcinoma Treatment), is a Phase 3 study. To learn more, call (866) 4-PROSTATE [(866) 477-6782)] or <clinical@dendreon.com>.

GVAX® Vaccine for Prostate Cancer Vs Docetaxel & Prednisone in Patients With Metastatic Hormone-Refractory Prostate Cancer

The purpose of this Phase III study is to compare the duration of survival between GVAX® prostate cancer vaccine and chemotherapy treatment. To learn more, contact the MEDFONE Call Center at (866) 679-4904

Docetaxel and Prednisone in Treating Patients With Hormone-Refractory Metastatic Prostate Cancer

Drugs used in chemotherapy, such as Taxotere (docetaxel) and prednisone, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Giving more than one drug (combination chemotherapy) may kill more tumor cells. It is not yet known which schedule of docetaxel and prednisone is more effective in treating prostate cancer. This randomized Phase III trial is studying two different schedules of docetaxel and prednisone to compare how well they work in treating patients with metastatic prostate cancer. Contact: Pirkko Kellokumpu-Lehtinen, principal investigator at (358) 247-3227 or <pirkko-liisa.kellokumpu-lehtinen@uta.fi>.

Docetaxel in Combination With GVAX ® Vaccine Versus Docetaxel and Prednisone in Prostate Cancer Patients

The primary objective of this Phase III study is to compare the duration of survival between patients receiving Taxotere in combination with the GVAX® vaccine for prostate cancer versus patients receiving docetaxel and prednisone treatment. To learn more, go to <www.clinicaltrials.gov> to find a location in your state.

DN-101 in Combination With Docetaxel in Androgen-Independent Prostate Cancer (AIPC) (AIPC Study of Calcitriol Enhancing Taxotere [ASCENT-2]

DN-101 is an investigational high-dose oral formulation of calcitriol, a naturally occurring hormone and the biologically active form of vitamin D. In high doses, calcitriol is believed to work in combination with many commonly used chemotherapy drugs in a way that may produce anti-tumor activity. This Phase III study is testing DN-101 in combination with docetaxel in a new dosing schedule and comparing it to the currently approved regimen of docetaxel plus prednisone (a drug that helps treat the symptoms of prostate cancer). To learn more, visit <www.ASCENT-2.com>.

CLINICAL TRIALS

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Docetaxel and Prednisone With or Without Bevacizumab in Treating Patients With Prostate Cancer That Did Not Respond to Hormone Therapy

This randomized Phase III trial is studying docetaxel, prednisone, and Avastin (bevacizumab) to see how well they work compared to docetaxel and prednisone in treating patients with prostate cancer that did not respond to hormone therapy. This Phase II trial is studying how well giving docetaxel, bevacizumab, and thalidomide together with prednisone works in treating patients with metastatic prostate cancer. To learn more, contact William Kelly, DO, protocol chair at (203) 737-2572.

Hormone Suppression and Radiation Therapy for 6 Months With/Without Docetaxel for High Risk Prostate Cancer

This randomized study is looking at the benefits of using docetaxel (chemotherapy) added to one of the standard treatments (radiation and hormones) for men with high-risk prostate cancer. To learn more, contact Anthony V. D'Amico, MD, PhD at (617) 732-7936.

Bortezomib and Mitoxantrone in Treating Patients With Advanced or Metastatic Androgen-Independent Prostate Cancer

Drugs used in chemotherapy, such as Novantrone® (mitoxantrone), work in different ways to stop tumor cells from dividing so they stop growing or die. Velcade (bortezomib) may stop the growth of tumor cells by blocking the enzymes necessary for their growth and may also make tumor cells more sensitive to chemotherapy. Combining bortezomib with mitoxantrone may kill more tumor cells. This Phase I trial is studying the side effects and best dose of bortezomib and mitoxantrone in treating patients with advanced or metastatic androgen-independent prostate cancer. To learn more, contact Clinical Trials Office, M.D. Anderson Cancer Center at (713) 792-3245.

When You Find a Clinical Trial

All clinical trials have guidelines about who can participate, so researchers will be able to identify appropriate participants in order to answer the questions they plan to study. The factors that allow someone to participate in a clinical trial are called "inclusion criteria" and those that disallow someone from participating are called "exclusion criteria." These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. If you believe you fit the criteria for a clinical trial, talk to your doctor further about the study and if it is right for you.

Additional Resources

Us TOO International: Clinical Trials and Studies section
http://www.ustoo.org/Clinical_Trials.asp

Find Clinical Trials listed with the International Federation of Pharmaceutical Manufacturers & Associations
http://www.ifpma.org/clinicaltrials.html

CenterWatch Clinical Trials Listing Service
http://www.centerwatch.com/

American Association of Cancer Research
http://www.aacr.org/

National Cancer Institute: NEW brochure: *Clinical Trials at NIH in Bethesda, MD*
http://www.ustoo.org/PDFs/clinical_trials_handbook1.pdf

COMMON CLINICAL TRIAL TERMS

Food and Drug Administration (FDA): The U.S. Department of Health and Human Services agency responsible for ensuring the safety and effectiveness of all drugs, biologics, vaccines, and medical devices.

Clinical Trials: Determine whether new drugs or treatments are both safe and effective in patients.

Protocol: A study plan carefully designed to safeguard the health of the participants as well as answer specific research questions.

Informed Consent: The process of learning the key facts about a clinical trial before deciding whether or not to participate.

Experimental Drug: A drug that is not FDA-licensed for use in humans, or as a treatment for a particular condition.

Standard Treatment: Treatments currently in widespread use and approved by the FDA; considered to be effective in the treatment of a specific disease or condition.

Phase I Trials: Initial studies to determine drug safety and effective in humans.

Phase II Trials: Controlled clinical studies conducted to evaluate the effectiveness of drugs for a particular indication(s) in patients with the disease or condition under study and to determine the common short-term side effects and risks.

Phase III Trials: Expanded controlled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide and adequate basis for physician labeling.