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Us TOO’S SNEAKERS@WORK DAY WILL BRING HIGH VISIBILITY TO PROSTATE CANCER – IT’S ABOUT TIME!

Sneakers@Work Day on June 15, 2007 aims to make millions of Americans aware that Prostate Cancer kills nearly as many men as breast cancer kills women. You know that the statistics are scary and now many more will know too.

AWARENESS is key. EARLY DETECTION is best. ACTION is critical.

Sneakers@Work Day is a sweeping cross-country workplace-based fundraising event just prior to Father’s Day, which will bring major attention to this devastating silent killer among men. Any company who participates will be wearing a badge of good will and support for men, across the country and the world. This a groundbreaking launch of a new campaign is certain to become as large as the Breast Cancer Awareness one, Lee Denim Day.

Sneakers@Work Day is easy:
- Companies pledge support
- Employees are encouraged to wear sneakers to work
- Each employee donates $5.00
- Every participant receives a pair of blue sneaker laces (blue represents prostate cancer as pink represents breast cancer)

We expect that within a very short time, thousands of companies and their hundreds of thousands of employees will know that Prostate Cancer is the #2 cancer fatality for men, that 30,000 men will die of the disease this year. That without public awareness Prostate Cancer will remain life threatening when it does not have to be. Our goal is to enroll at least 2,500 companies in the next few months. Make this your goal!

Action is Key! Commitment is critical. Sneakers@Work Day can only succeed with your help and involvement. Enroll your company, your wife’s, son’s, daughter’s company, friend’s company. Get local service clubs—Lions, Rotary, Elks, Kiwanis, Chamber of Commerce and others--to help. SPREAD THE WORD. Without companies making an active commitment to participate, awareness cannot grow, and we cannot accomplish for men what has been accomplished for women and Breast Cancer.

Encourage everyone you know to join Sneakers@Work Day. Join the fight. Make a difference. For more information, visit <www.ustoo.org> and click on the Sneakers@Work logo, or call Dan Reed at 630-795-1002 or <dan@ustoo.org>.

US TOO INTERNATIONAL PARTICIPATES IN COMBINED FEDERAL CAMPAIGN

For the first time ever, Us TOO International is now eligible to receive Combined Federal Campaign funds as a new member of the Health Service Charities of America (HSCA).

HSCA represents human service charities in workplace fundraising drives, and has participated in the Combined Federal Campaign, individual state and municipal campaigns, and private sector corporate campaigns.

All federal employees, including military personnel, will be participating in the 6-week Combined Federal fundraising Campaign from September 15 to December 15, 2006, and are able to complete pledge cards to make donations to their charities of choice.

Please share the Us TOO CFC number within your chapter and network of friends: CFC# 2865.

Thank you!
LOWER PSA THRESHOLD FOR BLACK MEN

African-American men with early, non-palpable prostate cancer have greater tumor volume than white men with similar prostate specific antigen (PSA) levels, a study shows. This suggests that the threshold for PSA should be lowered in black men. The widely used PSA blood test is used to look for early signs of prostate cancer. The traditional PSA cut off value is 4 ng/mL.

Based on the current findings, this value should be lowered to 2.5 ng/mL in African-American men "to increase the likelihood of finding cancers that are highly curable," Dr. Curtis A. Pettaway from The University of Texas M. D. Anderson Cancer Center, Houston, Texas told Reuters Health. The lower cut off value is especially important in African-American men less than 65 years of age and otherwise healthy, Pettaway said.

He and colleagues investigated whether there are pathologic differences by race in men with nonpalpable prostate cancer detected by elevated serum PSA levels alone. They found that African-American men had higher Gleason scores -- a measure of tumor aggressiveness -- than white men did, despite having similar PSA levels and preoperative prostate biopsy scores.

The Gleason score was upgraded after prostatectomy for 49 percent of the African-American men, compared to only 26 percent of white men. On average, specimens from African-American men had higher total tumor volumes and higher tumor volumes within given PSA strata than did specimens from white men. Their results were published in the July 1, 2006 issue of the journal Cancer.

The detection of higher tumor volumes in African-American men despite adjusting for serum PSA level suggests that, even in men with early disease, "the opportunity for cure after surgery may be lower among African-American patients if the same serum PSA threshold for biopsy is used for all races," the investigators explain.

"African-American men should be educated about prostate cancer and should consider getting tested beginning at age 40," Pettaway advised.

Reuters Health, 9 August 2006
On September 1, 2006, the Us TOO New York support group chapter of Us TOO International helped to kick off Prostate Cancer Awareness Month at a very exciting event sponsored by Cytogen Corporation and featuring a presentation by former New York City Mayor and prostate cancer survivor Rudy Giuliani.

The event held at The NASDAQ Stock Market heralded the opening of the trading day and includes guests from many other leading patient organizations including the American Cancer Society, the American Urological Association and the Prostate Cancer Foundation.

The event also launched Cytogen’s annual “Screen, Stage and Support” campaign designed to help patients, families and caregivers to learn about the role of proper diagnosis, treatment and support for men affected by prostate cancer.

This year Us TOO New York representatives Jack David Marcus and Rob Dublin stood on the NASDAQ stage alongside Michael Becker, CEO of Cytogen, and Mr. Giuliani. Mr. Marcus and Mr. Dublin also had a chance to share their perspectives as prostate cancer survivors with Mr. Giuliani in a special meeting prior to the event.

In his presentation, Mr. Giuliani noted that 235,000 cases of prostate cancer will be diagnosed this year and that one in every 34 men will die from the disease. He spoke eloquently about the fact that awareness and a regular check up probably saved his life.

Cytogen launched “Screen, Stage and Support” during Prostate Cancer Awareness Month 2001. Us TOO has been a supporter of this effort.

Through media interviews, patient education materials and free screening events with leading cancer organizations, the program helps men learn about the importance of early detection, proper staging and diagnosis, and the need to support people living with prostate cancer. During the ceremony, Mr. Becker spoke about Cytogen’s commitment to developing effective products to both treat and detect prostate cancer.

With Mr. Giuliani as guest speaker, this year’s ceremony attracted significant levels of media attention. Thousands of people all over the world saw this special event on television and cable networks including Bloomberg, Bloomberg Brazil, CNBC, Fox News, KTVU, CNBC India, NDTV (New Delhi India), ROB TV (Report on Business Canada) & New Tang Dynasty TV.

**PSA TEST HAS HIGHER ACCURACY TO DETECT PROSTATE CANCER IN PATIENTS TAKING FINASTERIDE**

Finasteride increases prostate-specific antigen (PSA) testing’s ability to detect prostate cancer, a study in the August 16 Journal of the National Cancer Institute reports.

Finasteride is a drug prescribed for men whose prostates have become enlarged. The drug decreases prostate swelling and helps men with urinary problems. However, an increased number of high-grade tumors in men taking finasteride in the Prostate Cancer Prevention Trial (PCPT) has some physicians worried about the effect of the drug.

Ian M. Thompson, M.D., of the University of Texas Health Science Center in San Antonio, and colleagues examined the PSA test’s ability to detect prostate cancer in the PCPT in men taking finasteride or a placebo. The group studied the PSA test’s sensitivity and diagnostic accuracy for both groups.

The authors found that finasteride changed the diagnostic characteristics of the PSA test so that it detected prostate cancer with higher sensitivity and accuracy in men in the finasteride arm of the PCPT than men in the placebo group. They suggest that the increased detection of high-grade prostate cancers in the finasteride arm of the PCPT may be related to the drug’s ability to improve the PSA test’s performance and not to it’s induction of high-grade disease.

The authors write, "This bias would be expected to contribute to greater detection of all grades of prostate cancer with finasteride."

*Journal of the Nat’l Cancer Institute 15 August 2006*
**DESPITE RAIN, BIG TURN-OUT FOR 2ND CHICAGO PROSTATE CANCER RUN WALK EVENT**

Sunday, September 10 was a gray day with light rain, yet nearly 1,000 people came out to Chicago’s Grant Park along the lakefront to participate in the 2nd Annual Greater Chicago Prostate Cancer Run, Walk ‘n Roll. The 5K run and 3K walk and is the only run/walk in the Chicagoland area dedicated to prostate cancer, and is co-sponsored by Wellness Place, a Palatine-based cancer resource center, and Us TOO International, a worldwide prostate cancer education and support network headquartered in Downers Grove, IL.

Proceeds from the event will be used to fund public awareness programs to educate men and their families about prostate cancer and the importance of early detection and treatment for long-term survival.

Support of this event and cause extended throughout the city. Illinois Governor Rod R. Blagojevich, Chicago Mayor Richard M. Daley and Senator Barack Obama were honorary chairpersons.

“My goal is to make Chicago a safer and healthier city by working together in partnership with organizations like the Greater Chicago Prostate Cancer Run Walk ‘n Roll to promote good health,” said Mayor Richard M. Daley.

"Through awareness and early detection we hope to continue fighting prostate cancer in the city."

At the race, the event’s emcee was WGN news anchor and prostate survivor Robert Jordan.

“Unfortunately, far too many men still die each year from prostate cancer,” Jordan said. “The good news is that catching the disease in its earliest stages helps. It saved my life.”

“We hope this event really gets people talking,” said Wellness Place Co-founder Myrna Porter, RN, a Barrington resident and wife of a prostate cancer survivor. “The more information people have, the more lives that can be saved.”

(Continued on page 5)
CHICAGO PROSTATE CANCER RUN WALK EVENT
(Continued from page 4)

Attendees enjoyed live music featuring popular Chicago cover band R-Gang, numerous activities for children and a free lunch. The Illinois and Chicago Departments of Public Health worked together to provide free PSA testing onsite – 40 men participated.

Fundraising and walking teams were made up of co-workers, family and friends, and area Us TOO chapters including Don Johnson and Mercy Hospital chapters. All attendees and sponsors promised to return next year.

Thanks to all the event participants and sponsors for chasing the rain away with their smiles! Special thanks go to presenting sponsor TAP Pharmaceutical Products, Inc.

Having experienced prostate cancer first hand I can attest to the shock of the diagnosis, the fear of staring death in the face, the anger of “why me?” the grief of possibly having my life shortened, the sadness of realizing how alone I am facing the uncertainties of treatment and recovery.

Prostate cancer is a disease that affects not only its victims but also those close to them. It’s a cruel ordeal for men, but it’s often made worse for their partners when they refuse to talk about it. Partners experience the same feelings of anger, fear and grief as their husbands, but when men refuse to openly discuss their feelings, their partners also feel helpless, frustrated, resentful and guilty. Unresolved feelings between a couple can seriously impair the communication in their relationship at a time when they need each other the most.

As we know, most men avoid talking about personal issues and even the most willing of us shut up tighter than clams when it has to do with our sexual health. To compensate we men get busy with technical matters and are usually willing to discuss the merits of surgery versus radiation or laparoscopic versus brachytherapy treatments as if we were talking about lawn mowers at Canadian Tire. When hit by the careen-

looking bus of irrationality and uncertainty, we retreat to the safety of logic and a rational choice of technology.

So what can you do if your spouse has opted to go through prostate cancer hell without you? Seeing cancer as a challenge to overcome rather than as an insidious disease eating away at your spouse is a good start. My advice is to support yourself and realize that thousands of women in Canada have gone through the same test as you. At times the dark thoughts and feelings can be overwhelming but try to take it one day at a time realizing that with time things will become clearer and less uncertain.

Find out if there is a prostate cancer support group in your area. If so ask if it has a spousal support group. Many prostate cancer support groups offer help and advice to the partners of men with prostate cancer. (see the sidebar for more information). Scan the web for on-line forums where you can find support from women in your position.

It is important to talk to someone knowledgeable who can help you work through feelings that come up for you. Health care professionals, therapists, coaches, or religious leaders are there to help support you in your time of need. Your doctor or local hospital may also be able to direct you to someone who will listen.

Every September is prostate cancer awareness month. If your spouse has received a diagnosis or is at risk, this is an excellent time to make yourself aware of the rich sources of information and support available to you and your partner. Don’t think twice to reach out.

Bradley Foster survived prostate cancer and is a better person for it. He now helps others by coaching men and their partners through the ordeals of cancer. He can be reached at <bfoster@giantstepscoaching.com> or by phone at (416) 537-7282.

US TOO PROSTATE CANCER EDUCATION & SUPPORT HOT SHEET - OCTOBER 2006
LOW-RISK PROSTATE CANCER PATIENTS FACE OVERTREATMENT

Many low-risk prostate cancer patients are being overtreated and might fare better if doctors monitored the cancer until treatment was necessary, a new study reports in the August 16th issue of the Journal of the National Cancer Institute. Past recommendations for early-stage prostate cancer patients involved prostate removal rather than monitoring the cancer's progress until treatment is necessary. But more recently, cancers are being detected at earlier stages, and reports that low-risk patients are being treated aggressively have made researchers suggest such treatment may not be the best solution. New studies suggest that aggressive treatment does not improve survival benefits and may harm patients' health.

John T. Wei, M.D., of the University of Michigan in Ann Arbor, and colleagues identified 24,825 men with prostate cancer between 2000 and 2002. They determined how many men were overtreated with prostate removal and 44% with radiation therapy. Assessing surgical outcomes for 168 biopsy Gleason 8 to 10 patients to investigate whether some patients have better outcomes after radical prostatectomy than others.

When the patients were stratified according to PSA level and percent positive biopsy cores into 6 groups, the authors report, there were no significant differences in clinical stage or Gleason score among the groups. However, patients with both a PSA value of 10 or less and less than 50% positive biopsy cores had better 5-year biochemical control rates (67%) than patients with higher values (23%), the researchers note. The authors conclude that "the ability to identify men with high-grade disease who are likely to harbor organ-confined or minimally extensive disease based on pretreatment prognostic factors may allow for selection of patients in this group who can receive short-term -- or even no -- androgen suppression without impacting on treatment outcome."

Reuters Health, 6 September 2006

RADICAL PROSTATECTOMY EFFECTIVE FOR SOME MEN WITH HIGH-GRADE PROSTATE CANCER

Men with lower PSA values and fewer positive biopsy cores are most likely to benefit from radical prostatectomy for high-grade prostate cancer, according to researchers.

“This retrospective analysis provides support for the widely held hypothesis that certain patients with high-grade prostate cancer can be identified who may be cured with local therapy alone," said Dr. Mark Hurwitz from Harvard Medical School, Boston, MA.

In the August issue of Urology (Urology 2006; 68:367-370), Dr. Hurwitz and colleagues note that they assessed surgical outcomes for 168 biopsy Gleason 8 to 10 patients to investigate whether some patients have better outcomes after radical prostatectomy than others.

When the patients were stratified according to PSA level and percent positive biopsy cores into 6 groups, the authors report, there were no significant differences in clinical stage or Gleason score among the groups. However, patients with both a PSA value of 10 or less and less than 50% positive biopsy cores had better 5-year biochemical control rates (67%) than patients with higher values (23%), the researchers note.

The authors conclude that "the ability to identify men with high-grade disease who are likely to harbor organ-confined or minimally extensive disease based on pretreatment prognostic factors may allow for selection of patients in this group who can receive short-term -- or even no -- androgen suppression without impacting on treatment outcome."

Reuters Health, 6 September 2006

SERUM ANDROGEN LEVELS IN BLACK, HISPANIC AND WHITE MEN

Litman HJ*, Bhasin S, Link CL, Araujo AB, McKinlay JB, and the BACH Survey Investigators

J Clin Endocrinol Metab, doi:10.1210/jc.2006-0037

Submitted on January 9, 2006; Accepted on August 3, 2006

Context: Racial/ethnic differences in androgen levels could account for differences in prostate cancer risk, body composition, and bone loss.

Objective: To investigate racial/ethnic variations in testosterone, bioavailable testosterone, dihydrotestosterone (DHT), sex hormone-binding globulin (SHBG) and dehydroepiandrosterone sulfate (DHEAS) levels.

Design: The Boston Area Community Health (BACH) Survey was a multi-stage stratified cluster random sample, recruiting from 2002-2005.

Setting: Community-based sample of Boston.

Participants: Black, Hispanic or White, aged 30-79 yr, competent to sign informed consent and literate in English/Spanish. Of 2301 men recruited, 1899 provided blood samples (538 Black, 651 Hispanic, 710 White).

Intervention: Data obtained during in-person at-home interview, conducted by bilingual phlebotomist/interviewer.

Main Outcome Measure(s): Testosterone, bioavailable testosterone, DHT, DHT/testosterone ratio, SHBG, DHEAS.

Results: With or without adjustment for covariates, there were no significant differences in testosterone, bioavailable testosterone or SHBG levels by race/ethnicity. DHEAS levels differed by race/ethnicity before covariate adjustment; after adjustment this difference was attenuated. Before adjustment, DHT and DHT/testosterone ratios did not significantly differ by racial/ethnic group. After adjustment, there was evidence of racial/ethnic differences in DHT (P = 0.012).
FREE BLUE RIBBON LAPEL PIN OFFER HUGE SUCCESS!!

As of Friday, September 15, 2006, 150 people have ordered more than 4,500 free blue ribbon lapel pins during Prostate Cancer Awareness Month!

“Originally the offer was to giveaway a maximum of 3,000 pins, but the response was so great, we went back to our sponsor and asked if they would be willing to increase their support so we could fulfill all requests,” said Pamela Barrett, Us TOO Director of Development. Special thanks to sponsor Valera Pharmaceuticals for initially supporting AND extending this offer!

Hold a Closest To The Pin Contest at your golf club this fall to benefit Us TOO and Arnie’s Army!

Visit www.ustoo.org for more information or contact Dan Reed at 1-800-808-7866 or dan@ustoo.org
ANDROGEN LEVELS
(Continued from page 6)

0.047) and DHT/testosterone ($P = 0.038$) levels; Black men had higher DHT levels and DHT/testosterone ratios than White and Hispanic men.

Conclusions: As there are no racial/ethnic differences in testosterone levels, normative ranges need not be adjusted by race/ethnicity for androgen deficiency diagnosis for men aged 30-79. Further investigation is needed to determine whether differences in DHT levels and DHT/testosterone ratio can help explain racial/ethnic variations in prostate cancer incidence, body composition, and bone mass.

New England Research Institutes, Watertown, MA, Section of Endocrinology, Diabetes, and Nutrition, Boston University, School of Medicine, Boston Medical Center
* Address all correspondence to: <hlitman@neriscience.com>..

DISCOUNTS TO FCRE / US TOO CONFERENCE EXTENDED
The Foundation For Cancer Research and Education (FCRE) and Us TOO International have announced that they will continue providing, at least until October 1, the discounted registration fees for the International Prostate Cancer Conference to be held at Reston, Virginia, October 19-22, 2006.

The Discount registration fee of $100.00 is extended to October 1, 2006. (Additionally, it will only be $95.00 if you sign up over the Internet).

Conference attendees can obtain a registration brochure through their Us TOO support group or by going to the FCRE website for information and a list of the speakers <http://www.cancer-foundation.org/conference_101906.html> or by calling 718-522-7512 and speaking to Jessie Myers or Rod Schecter.

The conference will be moderated by Snuffy Myers, MD.
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 through 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 (Continued on page 2)
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 antitumor 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 (continued from page 1)

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

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>.
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

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.