Us TOO® PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

April 2007

INSIDE THIS ISSUE

GPC Biotech Provides Satraplatin for Free

In February, GPC Biotech announced a new U.S. program that would provide its prostate-cancer treatment satraplatin to patients free of charge.

The program, known as the Satraplatin Expanded Rapid Access, or SPERA, is intended to provide the investigational drug to patients who have no other treatment options. Expanded access programs (EAPs) are intended to give patients access to investigational drugs to treat serious or life-threatening diseases or conditions for which there are no adequate therapies available.

"There is an important medical need for treatments for hormone-refractory prostate cancer (HRPC) patients whose first-line chemotherapy has failed," said Dr. Martine George, GPC Biotech's Sr. vice president of clinical development.

"We look forward to working with clinicians to make satraplatin available through the SPERA program to these patients who currently have no approved treatment options for their disease," George added.

GPC Biotech submitted its new drug application for satraplatin to the US Food and Drug Administration, which has granted fast-track status to the drug.

Satraplatin, an investigational drug, is

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Calcitriol with Docetaxel Boosts Prostate Cancer Survival

A new study suggests that an oral form of calcitriol (Asentar®, Novacea) combined with docetaxel (Taxotere®, Sanofi Aventis) may improve prostate cancer survival without increasing toxicity. The study was recently published in the February 20th issue of the *Journal of Clinical Oncology* (Vol. 25, pp. 669-74, 2007).

Researchers have been working to boost the effects of docetaxel, the standard of care, with a new high-dose activated vitamin-D pill. "These findings are very promising and exciting," principal investigator Tomasz Beer, MD, from the Oregon Health and Science University Cancer Institute, in Portland, told Medscape. "We'll need to confirm these results, but we're getting pretty close to the finish line."

During an interview, Dr. Beer emphasized that survival was not the primary end point for the study and will need to be confirmed in a phase 3 trial. And the study failed to produce a statistically significant improvement in its primary end point of PSA response. Overall, the response rate was 63% in the calcitriol-treated patients and 52% for placebo-treated patients (P = .07).

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The Year in Prostate Cancer

Adapted from MedPage Today (with permission)

Part III of this three part series highlights of the year in prostate cancer research in 2006. Summaries cover the roles of Health Food, Vitamins, Cholesterol and Prevention in prostate cancer. Like Parts I and II, relevant articles in 2006 HotSheets are cited. For fuller accounts, links to individual articles published in MedPage Today are provided.

Health Food and Vitamins

In the never-ending annals of cancer and nutrition, pomegranate juice, which may help stabilize PSA levels, had its day in the headlines, a finding not unnoticed by supermarkets, health-food stores, and upscale chefs.

According to a study a the University of California Los Angeles, drinking a glass of the anti-oxidant-rich juice each day increased PSA doubling time from 15 months to 54 months, certainly a boon to older patients.

- Pomegranate Juice Each Day Makes PSA Levels Stay

  <http://www.medpagetoday.com/HematologyOncology/ProstateCancer/tb/3690>

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CALCITRIOL + DOCETAXEL

(Continued from page 1)

In a press release explaining the setback, Dr. Beer told reporters, "During the past year, new work done by colleagues in the field has shown that only about half of survival can be explained by changes in prostate-specific antigen. Although PSA remains important, it has turned out to be a middle-of-the-road predictor of survival."

"If confirmed in a phase 3 trial, this represents a large difference in this disease, where randomized studies of 3 weekly docetaxel-based chemotherapy using mitoxantrone and prednisone as control therapy reported hazard ratios for death of 0.8 and 0.76."

The Androgen Independent Prostate Cancer Study of Calcitriol Enhancing Taxotere (ASCENT) is a double-blind randomized phase 2 study to evaluate the efficacy and safety of high-dose calcitriol, formerly known as DN-101, plus weekly docetaxel compared with placebo plus weekly docetaxel. ASCENT is the first placebo-controlled randomized study to test vitamin D for prostate cancer treatment. The trial is sponsored by Novacea and supported by Sanofi Aventis.

The study included 250 patients from 48 sites in the United States and Canada. Patients with progressive metastatic androgen-independent prostate cancer and adequate organ function received weekly docetaxel 36 mg/m^2 intravenously for 3 weeks of a 4-week cycle. Docetaxel was combined with either 45 µg of calcitriol or placebo taken orally 1 day before therapy. Survival benefits of the drug combination were confirmed by a multivariate analysis that showed that patients who received the combination had a 49% increase in survival vs. subjects taking docetaxel alone (P = .035).

During an interview with Medscape, Dr. Beer noted that patients in the combination group experienced less toxicity such as blood clots and gastrointestinal complications. "This was an unexpected finding of the trial," Dr. Beer said, "and will need to be confirmed in a future study."

Medscape Medical News
16 February 2007

ESTROGEN THERAPY: DES (DIETHYLSTILBESTROL)

Commentary by Malcolm Hendry, PhD, prostate cancer survivor and member of the Tex Us TOO Chapter in Houston, TX

DES has been a prostate cancer treatment for more than 40 years. It is classified as an estrogen and is a far less aggressive alternative than the "gold standards" radical prostatectomy and radiation. In the early years when DES was used at high dosages (5 mg a day), the drug worked well but unwanted thrombotic (cardiovascular) events were reported.

More recently, the accepted dosage of DES is 1 mg three times per day in conjunction with low-dose anticoagulant treatment. DES often gives favorable PSA response when Lupron response fails. DES is used for metastatic disease, for early prostate cancer, and as a rescue therapy.

Sale of DES in the US was discontinued in 1980, before today's proper use information was generated, but it is available from compounding pharmacies: A year's supply can cost as little as $200. The discontinuation may have occurred because of litigation relating to birth defects resulting from pregnant women using this hormone, coupled with the prior use of excessively high doses for men's prostate cancer.

There is little research on DES today because pharmaceutical companies only wish to develop new products that offer a huge financial return. But small scale research of DES today continues, including monitoring of PSAs and tracking tumor growth via imaging, after DES treatments. The use of estradiol (estrogen) transdermal patches is also being studied. Physicians today are frequently unfamiliar with proper DES utilization because of the momentum and investments in the "gold standard" violent treatments and very expensive LHRH inhibitor treatment.

DES does carry with it the consequences of further hormone shift, somewhat like Lupron, further reducing testosterone dominance. In addition, dehydration must be avoided.

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DOC MOYAD'S WHAT WORKS & WHAT IS WORTHLESS COLUMN— ALSO KNOWN AS "NO BOGUS SCIENCE" COLUMN

ZINC: Mega-doses=mega-problems (cue the dramatic music please)

Mark A. Moyad, MD, MPH
University of Michigan Medical Center, Department of Urology
***Email and for more information on general health now at: <www.drmoyad.com>**

Hey, zinc supplements are supposed to do everything for you. Some websites, alternative medicine magazines, and books say that high-dose zinc helps your immune system, cardiovascular system, prostate, and sex life, but to cut to the chase all of this stuff is B.S. (bogus science).

As a side note the zinc did not work for my sex life because my wife says that no pill can help someone who already is the perfect lover (I hope she was talking about me and not the Federal-Express guy).

If you believe all this hype on high-dose zinc supplements than you might also believe that I won the last mega-millions jackpot, but was abducted by aliens, and those little funny looking guys not only took my wallet with my winning ticket in it, but admitted they make all those crop circles in the farmers cornfields in the Midwest area of the U.S. Therefore, you need to please send me money now!

The largest randomized trial (3640 patients, 4 groups) of a combination daily dietary supplement (500 mg vitamin C + 400 IU vitamin E + 15 mg beta-carotene + 80 mg zinc + 2 mg copper) versus the combination without zinc, just 80 mg zinc, or placebo for age-related macular degeneration (AMD) found a significant reduction in the risk of disease progression over the 6-year study in the combination supplement that included zinc in it.

However, the only individuals that benefited were those with intermediate to advanced stages of already-diagnosed macular degeneration. Individuals at risk or with early stage macular degeneration did not benefit from taking this supplement over the study period.

This study was a landmark finding for eye health because it made a combination dietary supplement standard medicine for those with the dry form of macular degeneration. However, other studies since 2001 from Harvard to Greece have reported potential prostate and even cholesterol problems with high-dose zinc supplements.

A further analysis from the original eye health study in 2001 was just published and again demonstrates a potential urologic side effect with this high-dose supplement. There was an increase in hospitalizations for urologic causes such as kidney stones, urinary tract infection, and other urologic issues in patients on the high-dose zinc versus the non-zinc supplement from this study. Patients in this study were an average age of 69 years old and were followed for a little more than 6 years.

Let's review how much 80 mg of zinc supplementation daily is compared to the recommended daily intake of zinc from the government and this is found in the table below. Keep in mind that the recommended intake of copper is also listed here because one impacts the absorption of another. In other words, if an individual consumes too much zinc it impacts copper absorption, which can cause a variety of problems such as a type of anemia and overall immune suppression.

Most individuals that I see have no business taking high-dose zinc supplements because they have not been diagnosed with macular degeneration or any other condition that requires such a large intake of supplemental zinc. However, if you have the more advanced dry form of macular degeneration, there has to be a risk to benefit discussion with the eye doctor and the urology/oncology doctor.

In my opinion, if it is a matter of preserving your eyesight there should be some allowance of zinc in the product, but keep in mind that the average multivitamin carries only 15-20 mg and this has been found to be safe and should be the highest amount most individuals get from any pill.

References:

Johnson AR, Munoz A, Gottlieb JL, Jarrard DF: *J Urol* 177:639-643, 2007

Age-Related Eye Disease Study Research Group: Arch Ophthalmol 119:1417-1436, 2001.

Government guidelines for the recommended daily dietary allowances of zinc and copper

Age	Zinc (in milligrams)	Copper (in micrograms)
0-6 months	2	200
7-12 months	3	220
1-3 years	3	340
4-8 years	5	440
9-13 years	8	700
14-18 years	11 (male) & 9 (female)	890
19 years and older	11 (male) & 8 (female)	900 (0.9 mg)

THE YEAR IN PROSTATE CANCER *(continued from page 1)*

In other good news (at least for smokers), vitamin E supplements cut the prostate cancer risk for smokers by 71% and beta-carotene supplements reduced the risk for men with low baseline plasma levels of the antioxidant. The disappointing finding, however, was that neither antioxidant showed a benefit in the general population.

- Vitamin E Reduces Prostate Cancer Risk in Smokers

  <http://www.medpagetoday.com/HematologyOncology/ProstateCancer/tb/2686>

Finally, translating positive findings from heart disease to cancer remained frustrating. For example, Rand Health researchers found that eating fish rich in omega-3 fatty acids turned out to be ineffectual for cancer in general, despite the benefits it seems to have in warding off heart disease.

- Omega-3 Flounders as Cancer Protection

  <http://www.medpagetoday.com/HematologyOncology/ProstateCancer/tb/2545>

Us TOO comments:

An article in the March 2006 HotSheet describes in greater detail the disappointing results with fish oil as a cancer fighting antioxidant. It also covers a drug that may have the potential to boost the effect of lycopene (another antioxidant supplement) in food.

In an unrelated, but important note, Doc Moyad's column in the September 2006 HotSheet points out that pomegranate juice has recently been found to raise the blood levels of certain medications. However, Doc Moyad does mention that more research is probably needed to prove that this effect is as significant as it is with grapefruit juice. Please refer to his article to learn how this occurs and which medications can be affected.

Cholesterol

More contradictory results included the finding that men who self-reported high levels of cholesterol had about a 50% increased risk for prostate cancer, and if they were older than 65, the risk climbed to 80%, according to researchers in Italy. This finding, if borne out by additional research, might please statin makers.

- High Cholesterol May Be Prostate Cancer Risk

  <http://www.medpagetoday.com/HematologyOncology/ProstateCancer/tb/3035>

However, a meta-analysis of 26 trials by University of Connecticut investigators concluded that statins do not prevent cancer. Several highly publicized retrospective studies found that statins had a dramatic effect on several malignancies, including prostate cancer, but according to the researchers, these studies could not demonstrate causality. Analysis, found that the overall incidence of cancer was not reduced among participants using statins compared with control groups.

- Meta-Analysis Rules Out Statin Cancer Prevention

  <http://www.medpagetoday.com/HematologyOncology/ProstateCancer/tb/2421>

Prevention

Last, but not least, Texas researchers reported that Proscar® (finasteride) increased PSA sensitivity for both overall and high-grade prostate cancer but did not cause any extra aggressive malignancies, according to an analysis of more than 9,000 men.

- Proscar Exonerated as Trigger for High-Grade Prostate Cancer

  <http://www.medpagetoday.com/HematologyOncology/ProstateCancer/tb/3942>

Us TOO comments:

The October 2006 issue summarizes this article concerning the Prostate Cancer Prevention Trial and describes its controversial results in patients actively treated with finasteride.

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HUNDREDS DIAL IN TO LEARN ABOUT INTIMACY AND PROSTATE CANCER

Us TOO International hosted a very successful conference call on February 13th called **Intimacy and Prostate Cancer.** The response to this program was overwhelmingly positive. The complete transcript and audio replay are available on the website at <www.ustoo.org>.

This program featured Dr. Bullock, recognized in the 2005 publication, **Best Doctors in America.** Dr. Bullock specializes in treatment of cancer of prostate, bladder and kidney, including impotence (erectile dysfunction or ED) issues and solutions. The program also featured two couples who have faced this challenges and found solutions. Our couples were Jerry & Jo Ann Hardy of the Detroit, Michigan area, and Jim and Maureen "Mo" Kiefert, of Olympia Washington. Not only were our couples exceptionally articulate in communicating their struggles and success, both Jo Ann Hardy and Jim Kiefert serve on the Us TOO's Board of Directors.

While impotence is a common challenge with prostate cancer treatment, our panel acknowledged that it can be a highly emotional issue. Most importantly, the program focused on the fact that MANY solutions are available today. Some examples include:

- Oral medication (Viagra)
- Vacuum Pump
- Injections
- Implants

Amidst this list of clinical options, however, there was a practical core message to this one-hour program. Those couples who are most successful in reclaiming intimacy are those who:

- can acknowledge their feelings about the loss or shift in their intimate relationship
- are able to have frank discussions with their doctor and each other
- can keep the lines of communication open, even when it is difficult
- are committed to finding a solution and remain hopeful.

Complete transcript and audio replay available on the Us TOO International website, <www.ustoo.org>. For more info on ED and impotence solutions, search our website for "Post Treatment Issues."

PSA PRIMER—by Curtis Pesmen

It's helpful, it's must-do (for most); it's once-again controversial--PSA. And nearly 20 years after the FDA first approved its use for prostate cancer screening (1988) along with digital rectal exams, modern urologists, oncologists and patients now find the role of PSA changing almost annually.

Today, the standard of 4.0 ng/mL seems to be "dropping" a bit, as more and more experts follow the lead of William Catalona, MD developer of PSA as a tool back in the '80s, professor of urology at Northwestern University's medical school and head of the Urological Research Foundation. These leading-edge doctors--in hopes of reducing patients' morbidity and mortality--now order biopsies or watch patients more closely than they used to do, when patients' PSA levels move between 2.5 and 4.0 ng/mL.

This newfound vigilance at lower PSA levels has resulted in more early diagnoses, to be sure. And In 2005, a study by Harvard researchers found that men who have annual PSA exams are nearly three times less likely to die from prostate cancer than those who avoid yearly screening. But PSA testing also has likely caused overtreatment, and possibly unnecessary pain and suffering, among certain patients whose prostate cancer (or suspected cancer) may never have caused great harm or early death. (The more benign cases are called "indolent" cancer.)

"Researchers and urologists have had a love-hate relationship with PSA," says Kevin Slawin, MD, professor of urology and director of the Prostate Center at Baylor University, "in part because there are 40 different states of prostate cancer." This is another way of explaining why current predictive models (also known as nomograms) of recurrence, based primarily upon PSA, are inadequate for patients and docs alike.

As a result of new research and better prediction models, 2007 and 2008 may turn out to become key years in an era of PSA transition, in which prostate doctors of all stripes begin to embrace--and patients demand--more careful follow-up. Based upon new findings of the past few years, prostate doctors' tacks may soon change to more often include such newish, post-baseline measures as "free PSA," "PSA velocity," or, increasingly, "active surveillance" in place of "watchful waiting." In general patients should find, sooner rather than later, more closely-followed PSA--and related--measures. As Dr. Catalona, says: "The rate of rise in the PSA prior to a diagnosis of cancer... is a more powerful gauge of eventual recovery or death from prostate cancer than the actual PSA level itself." Key words here: Rate of rise. (See also New Engl J Med, July 2004).

Perhaps most important for patients to keep in mind these days is a comment made clear at The 2007 ASCO Prostate Cancer Symposium (American Society of Clinical Oncology, February), a recent annual meeting of prostate cancer doctors and oncologists in Orlando: "It's called prostate specific antigen--and NOT prostate CANCER specific antigen-- for a reason," Robert Getzenberg, PhD, of Johns Hopkins University Hospitals, said. As important as PSA readings may be, they aren't definitive. Still, these changes in the stature of the PSA test, often small but significant, don't always filter down to patients and support groups as quickly as we all would like. In short, the standard PSA scores "of old" don't mean quite the same thing as they did even a few years ago.

As with the evolution of cholesterol in regard to heart disease (we used to rely on just one number--whether total cholesterol was over or under 200), patients and candidate-patients are "managing" their numbers: trying to lower LDL (bad cholesterol), raise HDL (good cholesterol) and monitor the ratio between the three scores. Today, it makes more sense than ever for prostate cancer patients to know--or demand--their doctors present them with scores of "free PSA," "PSA velocity" after baseline scores have been taken, or be ever mindful of age-related differences in PSA, and differences in PSA testing equipment as well. In other words, as with cholesterol counts, the old numbers aren't bad. It's just that we now know we can prolong good health and survival, but updated the old PSAs and possibly adding a few key new notions.

Age-Adjusted PSA: What it means

In the "old" days of PSA readings, the 1980s, almost everyone wondered the same thing after getting their first combined digital rectal exam (DRE) and PSA test: "Am I over or under 4.0?"

In general, several leading national health groups and prostate cancer specialists recommend a baseline PSA test for all men by age 40, and at age 35 for men who may be at high risk due to family history, obesity (it muddles PSA scores) or African American heritage. And while today's doctors don't quite agree on all the numbers, they do agree that PSA levels change with age--naturally. So, too, should prudent screening and treatment targets.

For example, those aged 40-49 with values of 0 to 3.0 ng/mL are considered normal; while those showing scores of over 10 are considered moderate-to-highly elevated. For those aged 50-59, PSA values of 4.0 to 5.0 ng/mL are considered normal; with scores over 20 considered moderate-to-highly elevated.

Finally, for those ages 60-70+, PSA scores of 4.0 to 9.0 ng/mL are considered normal, while measures over 20 are again considered at least moderately elevated. A lot of gray area remains in between these ranges, which is why more specific measures are needed.

Free PSA: What it means

A normal PSA test is a "total" measure of PSA. It includes both "bound" PSA, or antigens attached to proteins, and "free" PSA, which are free-floating antigens in the bloodstream that are not

(Continued on page 7)

ESTROGEN THERAPY

(Continued from page 2)

There are many men, including the writer and the past president of Tex Us TOO, who believe they are alive today because of DES given after standard treatments had failed and their cancer physicians gave up on them. DES should be one of every cancer physician's treatment options if patient quality of life is paramount, not just profits.

The information and opinions expressed in this commentary are not recommendations for any medical treatment, product service or course of action by Us TOO International, Inc., its officers and directors, or the editors of this publication. For medical, legal or other advice, please consult professional(s) of your choice.

US TOO UNIVERSITY PATIENT EDUCATION SYMPOSIUM IN AUSTIN, TX FOCUSES ON "LIVING WELL WITH PROSTATE CANCER"

Us TOO International is thrilled to announce the program schedule for our upcoming Us TOO University in Austin, Texas. Us TOO University kicks off Friday, May 11, with the Patient Education Symposium called "Living Well with Prostate Cancer."

With more men living longer with prostate cancer, and the awareness that overall health is not simply the absence of disease, this event addresses a full range of vital topics. Open to the public, patients, spouses, partners and family members in Austin and the surrounding communities are welcome to attend this FUN, interesting, educational and timely event.

"Living Well…" offers something for everyone; from sessions on the most innovative treatment options, to the importance of physical fitness to your recovery and overall health, a session for couples about intimacy and prostate cancer and so much more. Once again, we will have delicious, nutritious and abundant refreshments, many exhibitors, as well as expanded time and space to explore all the exhibits.

Featured sessions and speakers include:

- DaVinci surgical procedure with surgeon, Randy Fagin, MD
- Incontinence solutions with Kimberlee Sullivan, DPT
- Intimacy & Prostate Cancer with patient cancer survivor Jerry Hardy and his wife, Jo Ann
- Emerging Solutions & Clinical Trials

AND

- "My Prostate Cancer Journey" with Sam Cox, Austin native, prostate cancer survivor, past president of the Austin Police Association, and recognized Austin radio personality for the KLBJ morning radio show on 590 AM.

Friday night's symposium kicks off Us TOO University's two-day event. Saturday sessions are closed to the public and focus on sharing, teaching, and empowering Us TOO chapter support group leaders with exceptional information and countless tools.

(Current and future chapter leaders, see the chapter leader section of the website for early-bird registration forms for both day's events.)

Watch the website <www.ustoo.org> for additional information about this event and registration forms for Friday's symposium.

Special thanks to our Host, Us TOO Austin South Region Chapter, and to Platinum Sponsor Sanofi-aventis and all the corporate sponsors and exhibitors for their support of this program.

"Living Well with Prostate Cancer" Us TOO University Patient Education Symposium

Hyatt Regency Austin on Townlake
Friday, May 11, 2007
4:30 pm - 10:00 pm

- Open to the public
- Refreshments and exhibits start at 4:30pm
- $5.00 per person pre-registered
- $10.00 per person day of event
- ($15.00 per couple day of event)
- Pre-Register online at <www.ustoo.org/university>

NEW PRODUCT FOR CHEMO, DIALYSIS PATIENTS

When a young friend of Mary Hogan's children was undergoing chemotherapy treatment, Hogan came up with a unique way to help the girl and her family. Hogan, of Morris IL, invented and patented a specially designed shirt for children and adults undergoing chemotherapy and dialysis. The Medical Dignity Garment also is appropriate for people requiring any medical treatment through a port or central line.

The white-button-down shirt helps both the patients and caregivers, Hogan says." My garment improves the caregiver's ability to administer treatment in a number of ways. Treatments are simplified because of the ease of access: it eliminates any concern of a patient being exposed. It also provides time-saving benefits to caregivers."

The shirt features tear-away panels on the front of the shirt and on its sleeves. The panels are attached with Velcro and are located in areas where ports or shunts are typically administered, allowing the patient to remain fully dressed, warm and comfortable during treatment. Patients then can go back to work or social activities, knowing that the panels are covering the evidence of there treatment.

Hogan is pleased that the shirts, which are available in children's sizes and adult sizes for men and women, provide the wearer with a peace of mind. "Chemotherapy, dialysis and other infusion treatments are often administered in a common room offering very little to no privacy. Our garment renews a feeling of control, modesty and ease during treatment at a very difficult time of their lives."

Sarah, who was the first person to use the Medical Dignity Garment, is now a teenager. She remembers how the shirt helped her endure treatments, thanks to Hogan's idea. "Mary's outfit made my chemo at the hospital easier...[The] special outfit that she had made for me let them access my port through an opening. When the kids at the hospital saw my special outfit, they wanted one too."

For further information or to order a Medical Dignity Garment, please call (815) 941-4894 or visit their website <www.medicaldignity.com>.

PSA PRIMER *(continued from page 5)*

attached to proteins. When doctors order a "free PSA," they are looking at a RATIO of PSA measures--the percentage of free PSA to total PSA. When you think about it, this is akin to the newer cholesterol counts in regard to heart health. (We used to measure total cholesterol, one count--above or below 200--remember? No HDLs or LDLs, "good" or "bad" cholesterol?)

Experts including Alan Partin, MD, noted pathologist of the Brady Urological Institute at Johns Hopkins University in Baltimore, and many others now believe, in short, that the higher the "free" PSA reading (greater than 14 to 25 percent), the more likely it is that you are free of prostate cancer. Those who are found to have low levels of free PSA are more likely to be diagnosed with cancer.

In addition, citing one key study at Hopkins, Dr. Partin adds that use of the free PSA test allowed doctors to avoid 20 percent of patients' biopsies that would have been found to be negative if older measures were used. However, 18 percent of patients--were found to have prostate cancer even in the "old, safe" 2.5 to 4.0 ng/mL range--which led researchers to recast the PSA numbers into more helpful, predictive tools.

PSA Velocity (PSAV): What it Means

As we've seen, PSA tests aren't perfect. And that's not their fault! PSAs are sensitive assays, which can rise quite high due to irritation or inflammation of the prostate gland. Likewise, PSA scores can dive when, or after, inflammation of the gland subsides. Remember Dr. Catalona's caution (above): The PSA rate-of-change is often what matters most.

Then, too, some men's prostate glands are simply considered "leaky" in terms of PSA, meaning more antigen leaks out into the bloodstream for a variety of reasons; some known, some unknown. This, too can result in frighteningly high counts that don't necessarily mean cancer or prostate cancer recurrence.

For these reasons and more, PSAV--in short, the rate of change of PSA over one year--has gained ground over the past few years as a key component of prostate cancer diagnosis. The numbers to watch are again age-related but helpful to those of all ages: Within a "normal" range, 2.5 to 5.0 ng/mL, a man must be watched more closely--or at times biopsied, experts say, if his PSA rises more than 0.75 ng/mL over 12 to 18 months. (Note: a man may need two or three tests over a year-and-a-half to track this type of rise.)

Urinary PCA3 Test: What it Means

One other type of test that was heavily studied and now FDA-approved--looks at two (relatively) unfamiliar components to PSA-type testing: urine and prostate genes. At one heavily-attended seminar at the February ASCO event, Leonard Marks, MD of Urological Sciences Research Foundation explained how this new test will benefit patients. Most important: For those who face repeated biopsies, after high PSAs but no-cancer-found, this new assay may help greatly.

By isolating a prostate cancer gene (which was first discovered in the early 1990s at Johns Hopkins University) researchers have advanced the science to where they can use PCA3 scores to predict outcomes of a biopsy. Sounds convoluted, but it tells one important finding: whether PSA has risen because of benign inflammation--or whether cancer is causing PSA to spike.

And this follow-up test can be done without needle sticks, nor biopsies. Plus, it could spare millions of men from undergoing unnecessary and painful biopsies in the future-- if it proves to be as successful as early tests show. Of course, initial PSAs readings are still necessary, for now, in order to highlight who is a proper candidate for PCA3. (Technology for the test itself is licensed by Gen-Probe, Inc., of San Diego.) And pricing has yet to be determined.

SEMEN-BASED GENE PSA TEST: What it Means

Go ahead: call it Ejaculation Speculation. Researchers have developed a new, non-invasive test for prostate cancer that is both highly accurate and

Company and Group Registration Deadline Extended to Monday, April 16! Sign up Today!

JUNE 15, 2007

SNEAKERS @ WORK

THE DAY FOR NATIONAL PROSTATE CANCER AWARENESS & ACTION

Participate in our WORKPLACE GIVING program to support prostate cancer patient education and support efforts!

Visit www.ustoo.org/sneakers@work for more information or contact Dan Reed at 1-800-808-7866 or dan@ustoo.org

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

ARNIE'S ARMY BATTLES PROSTATE CANCER

Visit www.ustoo.org for more information or contact Dan Reed at 1-800-808-7866 (dan@ustoo.org)

*All proceeds from donations and items sold benefit **Us TOO's** FREE programs, support services and educational materials for prostate cancer patients and their families*

PSA PRIMER

(Continued from page 7)

based on markers (antigens, like PSA) naturally found within semen. The only apparent downsides? The test isn't yet on the market--and hasn't yet been tested on tens of thousands of men.

The new test, which was born at Harvard Medical School, and under development at Egenix, Inc., New York, and Proteome Systems of Australia, may be available by 2009 or 2010. Meanwhile, researchers will try to speedily perfect sample collection methods (temperature affects sperm, so home tests/transported samples may pose problems) to ensure accuracy and reliability.

POST SCRIPT

"Back in '89, I had my prostate cut out," says Jim Kiefert, an 18-year survivor and chairman of Us TOO International, in an interview for the book, 'Your Prostate Cancer Survivors' Guide.' "And to this day, my PSA still goes up and down."

So yes, our bodies continue to surprise us, pre- and post-cancer diagnoses. Yet soon, it seems--finally, it seems--PSA readings won't be able to surprise us--as much.

SATRAPLATIN FOR FREE

(Continued from page 1)

a member of the platinum family of compounds. Over the past two decades, platinum-based drugs have become a critical part of modern chemotherapy treatments and are used to treat a wide variety of cancers. Unlike the platinum drugs currently on the market, all of which require intravenous administration, satraplatin is an orally bioavailable compound and is given as capsules that patients can take at home.

In September 2006, GPC Biotech announced top-line results for the double-blinded, randomized satraplatin Phase 3 registrational trial, the SPARC trial (Satraplatin and Prednisone against Refractory Cancer). The trial is evaluating satraplatin plus prednisone versus placebo plus prednisone as a second-line treatment in patients with HRPC.

SPERA is only available through physicians enrolled in the program. To find participating sites, search for satraplatin at <www.clinicaltrials.gov>. Please remember to refine your search specifically for the HRPC trial.

CYTOGEN LAUNCHES PSMA ANTIBODY TRIAL

Cytogen has announced the initiation of the first human clinical study of CYT-500, a radiolabeled monoclonal antibody that targets prostate-specific membrane antigen (PSMA). The Phase I trial will investigate the safety and tolerability of CYT-500 and determine the optimal antibody mass and therapeutic dose for further studies. The trial is expected to enroll up to 36 patients.

CYT-500 employs the same monoclonal antibody as Cytogen's molecular imaging agent Prostascint® but it is linked to ^{177}lutetium, a particle emitting therapeutic radionuclide. This novel product candidate is designed to enable targeted delivery of high doses of radiation to PSMA-expressing cells. PSMA is a protein abundantly expressed on the surface of prostate cancer cells, with an increased expression in high-grade, metastatic and hormone-refractory prostate cancers.

Unlike PSA, PAP and prostate secretory protein, PSMA is a membrane glycoprotein that is not secreted, making it an excellent therapeutic target.

FDA News Drug Pipeline Alert
27 February 2007

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US TOO PROSTATE CANCER EDUCATION & SUPPORT
HOTSHEET

SPECIAL BURNING ISSUES SUPPLEMENT

APRIL 2007

THIS SUPPLEMENT TO THE *US TOO PROSTATE CANCER HOT SHEET* WAS MADE POSSIBLE BY UNRESTRICTED EDUCATIONAL GRANTS FROM

CYTOGEN GPC biotech

HIGHLIGHTS FROM THE 2007 MULTIDISCIPLINARY PROSTATE CANCER SYMPOSIUM—FEBRUARY 21-24, 2007, ORLANDO, FL

ORAL SATRAPLATIN AS SECOND-LINE THERAPY IN ADVANCED PROSTATE CANCER

The investigational drug satraplatin significantly reduced the risk for disease progression in a phase 3 trial in advanced prostate cancer. The oral drug is currently awaiting Food and Drug Administration (FDA) approval.

Satraplatin could offer "a valuable second-line treatment option for men with hormone-refractory prostate cancer," said lead investigator Daniel Petrylak, MD, from New York Presbyterian Hospital. There are no standard second-line options for these patients at present, he pointed out. Dr. Petrylak was speaking at the Multidisciplinary Prostate Cancer Symposium in Orlando, FL.

An FDA approval application for satraplatin, based on this data, was filed by GPC Biotech Inc. in February. The drug was granted fast-track designation, so it may be available in late 2007.

The phase 3 trial, known as the Satraplatin and Prednisone Against Re-

(Continued on page 3)

NEW CLINICAL DATA FOR PROSTASCINT® IN PROSTATE CANCER PRESENTED AT THE 2007 PROSTATE CANCER SYMPOSIUM

Cytogen Corporation (NASDAQ: CYTO) recently reported that clinical investigators from leading cancer research centers presented data from recent and ongoing clinical trials of PROSTASCINT® (capromab pendetide) in prostate cancer. The six PROSTASCINT-related presentations were highlighted by two studies that evaluated the outcomes of prostate cancer patients based on the image findings of PROSTASCINT. The two major studies are summarized below.

Eight-year biochemical disease free survival following permanent prostate brachytherapy with dose escalation in biologic target volumes identified with SPECT/CT capromab pendetide (Abstract No. 357).

This is the first of the two outcomes studies presented related to eight-year survival outcomes data from a prospective, comparative clinical trial using PROSTASCINT fusion imaging. The study utilized PROSTASCINT fusion imaging to assess local and distant disease and to alter the radiation dose to areas of suspected high tumor burden to enable more efficient and precise targeting of brachytherapy.

PROSTASCINT fusion imaging combines anatomical images from computed tomography (CT) or magnetic resonance imaging (MRI) with functional images from single-photon emission computed tomography (SPECT) using PROSTASCINT. Data from the study indicate that individualizing seed implantation regimens results in high rates of biochemical disease free survival (bDFS) in these patients.

Importantly, patients whose PROSTASCINT fusion image showed their cancer to be limited to the prostate gland had significantly higher bDFS than those whose image showed uptake outside the prostate. "PROSTASCINT brings a new level of precision to prostate cancer imaging by providing a clearer view of the location and extent of disease in and around the prostate," said Rodney J. Ellis, M.D., a radiation oncologist and assistant professor of urology with the Case School of Medicine, and the lead investigator in the study.

"Beyond its approved indication in imaging disease, by visualizing the tumor within the prostate gland, PROSTASCINT may help deter-

(Continued on page 2)

Co-Sponsors of the 2007 Prostate Cancer Symposium

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SUO Society of Urologic Oncology

NEW CLINICAL DATA FOR PROSTASCINT® *(continued from page 1)*

mine where to deliver the highest doses of radiotherapy to individual patients -- increasing the chances of disease-free survival while attempting to limit treatment-related side effects," added Dr. Ellis.

The study evaluated the use of PROSTASCINT fusion imaging to define brachytherapy treatment regimens for 239 newly-diagnosed prostate cancer patients. It utilized two sets of criteria for evaluating biochemical failure: the standard ASTRO consensus criteria and the newer Radiation Therapy Oncology Group (RTOG)-ASTRO Phoenix Consensus Conference definition.

Overall, the eight-year bDFS rate was 88.2% using the ASTRO criteria and 82.5% by the Phoenix definition. PROSTASCINT findings of prostate-confined disease correlated with bDFS rates of 91.7%, while patients with periprostatic (near the prostate) and distant disease had bDFS rates of 72.7% and 66.7% by ASTRO criteria ($p = 0.0003$) and were 86.6%, 71.6% and 56.8% ($p < 0.0001$) by Phoenix criteria.

When stratified according to low, intermediate and high risk groups, bDFS rates were 96.1%, 86.0% and 74.2% by ASTRO and 89.8%, 84.1% and 66.2% by Phoenix criteria, respectively.

Prediction of prognosis for prostate cancer patients with central abdominal uptake on capromab pendetide (PROSTASCINT) (Abstract No. 173).

The second outcomes study investigated patients whose PROSTASCINT images showed uptake in the central abdomen as compared to those without such findings. Central abdominal uptake (CAU) of PROSTASCINT is difficult to confirm pathologically; therefore, outcomes in patients with this finding are important.

In the study of 341 men with prostate cancer who underwent PROSTASCINT imaging, PROSTASCINT detected CAU in 69 or 20% of the patients. Patients were followed for a median of four years and prostate cancer-specific death rates were 10 times greater in the CAU group ($p=0.005$). Furthermore, the increased death rates were independent of the use or timing of intervention with hormone therapy.

"Although there has been uncertainty about the meaning of central abdominal activity on these scans, most physicians experienced in the use of PROSTASCINT believe that this multifocal abdominal pattern represents metastatic disease in retroperitoneal and/or mesenteric lymph nodes," said Michael Manyak, MD, vice president of medical affairs with Cytogen.

"This outcomes study is striking because, with limited existing histopathologic correlation, the data show that this pattern of uptake with PROSTASCINT is associated with a poor prognosis. This is now the third study to show a bad prognosis in patients with signal outside of the pelvis, Dr. Manyak Added."

2007 Prostate Cancer Symposium
BUSINESS WIRE, 24 February 2007

TOREMIFENE MAY EASE ANDROGEN DEPRIVATION COMPLICATIONS

The selective estrogen receptor modulator toremifene (Acapodene) improved lipid profiles and increased bone mineral density (BMD) in androgen deprivation therapy for advanced prostate cancer. So it emerged from a pair of analyses of early interim data from a trial of nearly 1,400 patients, findings that were reported at the 2007 Multidisciplinary Prostate Cancer Symposium by Matthew Smith, MD, PhD, of the Massachusetts General Hospital Cancer Center.

"These interim results suggest that toremifene has the potential not only to reduce the risk of fractures in men with advanced prostate cancer, but also to im-

(Continued on page 4)

NEW ANDROGEN RECEPTOR TEST MAY PREDICT PROSTATE CANCER AGGRESSIVENESS

Researchers have developed a new tool that may predict whether a patient's prostate cancer will progress after surgery. The tool is the first to measure the amount of androgen receptor protein present in a single cancer cell. Androgen receptors are proteins present in normal as well as cancerous prostate cells, and play a role in prostate cancer progression by acting as binding sites for androgens that fuel cancer growth.

"We have created a highly sensitive predictive test for prostate cancer, similar to those available for breast cancer, that can be used to predict disease progression and potentially impact its course," said Michael Donovan, MD, PhD, Senior Vice President of Research and Development at Aureon Laboratories, Inc., and lead author of the study. "Our data suggest that a high level of androgen receptors in prostate tumors is associated with cancer progression and metastasis."

In this study, researchers used a technique called quantitative immunofluorescence to measure androgen receptors and other molecular markers in prostate tissue from 881 men who had radical prostatectomy at Memorial Sloan-Kettering Cancer Center between 1985 and 2003. They combined the data with clinical variables and image analysis to create a tool for predicting whether a patient's prostate cancer might spread, and how quickly, within five years after surgery.

The researchers found that the tool was 84% accurate in predicting the spread of prostate cancer. The study also found that the risk of cancer progressing increased with an increasing level of androgen receptors in a single prostate cancer cell. The authors note that androgen receptor

(Continued on page 4)

Analysis Finds External Beam Radiation Therapy Less Effective than Radioactive Seed Implants or Surgery for Early Prostate Cancer

A new analysis from the Cleveland Clinic found that men who receive external beam radiation therapy (EBRT) for early-stage prostate cancer do not live as long as those treated with radioactive seed implants (brachytherapy, SI) or surgery (radical prostatectomy, RP) to remove the prostate.

The study is the first to assess the effect of the three treatment strategies upon overall survival.

"These findings indicate that the three major forms of treatment for early-stage prostate cancer are not necessarily equivalent in terms of overall survival," said Jay Ciezki, MD, Staff Physician in the Cleveland Clinic's Department of Radiation Oncology and the lead author. "Moreover, these findings persisted after controlling for potential confounding factors (age, other illnesses, and smoking history)."

Dr. Ciezki and colleagues analyzed five-year overall survival among 2,285 men with low- or intermediate-risk prostate cancer: 662 men treated with SI, 570 men treated with EBRT, and 1,053 men treated with RP.

All patients were treated at the Cleveland Clinic between 1996 and 2003. The researchers controlled for factors such as Charlson score (a measure of a patient's general health, including other illnesses), age, smoking status, cardiovascular health, and alcohol use, among others.

After five years, 93.8% of the men who received EBRT were still alive, compared with 95.7% of those who received SI and 97.7% of those who had RP. After controlling for confounding factors, SI and RP were found to be equally effective, while EBRT remained less effective. Smoking, increasing Charlson score, and age were also independently associated with reduced overall survival.

Abstract # 293 "A Comparison of Overall Survival between Patients with Low and Intermediate-Risk Prostate Cancer Treated with Brachytherapy, External Beam Radiotherapy, or Radical Prostatectomy." J. P. Ciezki, C. A. Reddy, P. A. Kupelian, et al.

2007 Prostate Cancer Symposium
ASCO press briefing
24 February 2007

Antisoma Drug Found Effective in Advanced Prostate Cancer Phase II Trial

Antisoma, a London based company, announced at the ASCO Prostate Cancer Symposium positive phase II trial interim results in hormone-refractory prostate cancer patients in a combination treatment with AS1404. The results showed that PSA response rates were higher in the AS1404-docetaxel combination (57%) than with docetaxel alone (35%). Time to tumor progression and survival data will be reported later in the year, but current data shows that the frequency of PSA progression was halved in the AS1404-docetaxel combination versus docetaxel alone (17% versus 29%). Safety statistics indicate no significant increase in side-effects from AS1404.

AS1404 (5,6-dimethylxanthenone-4-acetic acid [DMXAA]) is a flavonoid that induces the synthesis of TNF alpha in tumors. This shuts down the tumor vasculature similar to that seen with direct administration of TNF alpha. DMXAA is considered a *vascular disrupting agent since it interferes with the vascular or blood vessels of tumors.* DMXAA has been shown to augment the antitumor effects of melphalan, cisplatin, cyclophosphamide, paclitaxel, radioimmunotherapy, radiation, immunotherapy, and hyperthermia.

2007 Prostate Cancer Symposium
Antisoma press release, 24 February 2007

Second-Line Satraplatin

(Continued from page 1)

fractory Cancer (SPARC) study, involved 950 patients who had failed on at least 1 prior chemotherapy agent. Dr. Petrylak explained that the trial was designed in 2003, before docetaxel was approved for first-line treatment of prostate cancer, and hence some of these patients had been treated with other agents, including mitoxantrone. All participants received prednisone, a standard therapy for hormone-refractive prostate cancer, and were randomized to receive either satraplatin or placebo.

The primary end point was progression-free survival (PFS), and progression was assessed on a "clinically relevant" composite of radiologic data, skeletal events, symptoms, and death, Dr. Petrylak explained. PFS was significantly increased in the group treated with satraplatin plus prednisone (median PFS, 11.1 weeks) compared with those on prednisone alone (median PFS, 9.7 weeks). The hazard ratio was 0.67 (95% CI, 0.57 – 0.77), which was presented in the ASCO press release as showing a 33% reduction in the risk for disease progression (Prostate Cancer Symposium, Abstract 145, presented February 23, 2007).

"There was a lot of discussion about satraplatin at the symposium this year," Kevin Kelly, MD, from Yale University, in New Haven, Connecticut, told Medscape. "It did hit its primary end point, and it did show some mild clinical benefits to patients, but the controversy centers on the size of the effect that was seen in this trial — the difference between the median PFS was a total of 10 days, and so the question being asked is whether this is really a benefit."

Dr. Kelly, who was not connected with the trial, said that he felt there was a benefit from the drug — although the difference in the median time was not large, the survival curves did separate and were continuing to separate. "It seems as patients take the drug longer, they do

(Continued on page 4)

Androgen Deprivation Therapy (ADT) May Increase Risk of Death from Heart Disease

Researchers from Harvard Medical School have found that ADT for localized prostate cancer may be associated with increased risk of death from heart disease in men aged 65 and older.

"ADT is associated with elevated body mass index, increased body fat deposits, and diabetes, all of which raise the risk of death from heart disease," explained lead author Henry Tsai, MD, a Resident in the Harvard Radiation Oncology Program. "Although our findings demonstrated that older men receiving this treatment may be at increased risk, even after taking into account other cardiovascular risk factors, a prospective clinical trial would be needed to confirm a cause-and-effect relationship."

Many men receive ADT in addition to other treatments for localized prostate cancer, with the aim of reducing the level of cancer-fueling testosterone in the body. Drawing from the CaPSURE database, a national registry of men with prostate cancer, Dr. Tsai and colleagues compared cardiac and total mortality between 735 men with localized prostate cancer who received ADT (for 1 to 32.9 months, median duration 4.1 months) and 2,901 men who did not receive ADT.

After controlling for other cardiovascular risks (such as diabetes, hypertension, body mass index, and smoking), the duration of ADT was significantly associated with a shorter time to both death from heart disease and death from all causes. When analyzed by age, the association between ADT use and death remained significant in men age 65 and older, but not in those under age 65. After five years, 3% of older men who received ADT died of cardiac causes, compared with only 0.9% of men who did not.

Abstract # 298 "Androgen Deprivation Therapy for Prostate Cancer and the Risk of Cardiac Mortality." H. K. Tsai, A. V. D'Amico, N. Sadetsky, et al.

2007 Prostate Cancer Symposium
ASCO press briefing, 24 February 2007

Toremifene & Androgen Deprivation Complications

(continued from page 2)

prove cholesterol levels, addressing another significant side effect of a standard treatment for this disease," he said. Androgen deprivation has been shown to decrease bone mineral density and increase fracture risk. It is also associated with increased total cholesterol and a 26% increase in triglycerides, and an increased risk of coronary heart disease.

Toremifene is also being studied for preventing prostate cancer and is marketed under the brand name Fareston for the treatment of breast cancer.

The study recruited 1,392 men ages 50 and older at several centers in the US and Mexico. Participants were randomized to toremifene (80 mg/day) or placebo for two years. Results from first 197 patients completing 12 months of therapy revealed significantly increased BMD at the lumbar spine ($P<0.001$), at the hip ($P=0.001$) and at the femoral neck ($P=0.009$) compared to the placebo group who lost bone at all three sites.

Interim analysis of toremifene's effects on lipid levels showed:

- An 8% reduction in total cholesterol vs. a 1% decline with placebo ($P=0.001$).
- An 8% decrease in LDL cholesterol vs. a 1% increase with placebo ($P=0.003$).
- A 1% increase in HDL cholesterol vs. a 5% decline in HDL with placebo ($P=0.018$).
- A 13% decrease in triglycerides vs. a 7% increase with placebo ($P=0.009$).
- A decrease of 7% in the total cholesterol/HDL cholesterol ratio versus a 6% increase in the placebo group ($P<0.001$).

Dr. Smith cautioned that it was too early to conclude that the changes would result in fewer fractures or cardiac events. Both fracture rate and cardiac events will be evaluated after 24 months of treatment.

"Years ago we were not that concerned about bone loss and lipids because these patients were not expected to have extended survival," said Kevin Kelly, DO, of the Yale Cancer Center. "But now we are starting to give androgen deprivation therapy for 10 to 15 years," Dr. Kelly continued. "We are giving it to younger men now for longer periods of time, so these long-term side effects are now becoming more worrisome."

Dr. Kelly, who was not involved in this study, also cautioned about the possible risks of long-term toremifene treatment. "We don't know whether these drugs will have similar thrombotic side effects as do other of the selective estrogen receptor modulators," he said.

Smith, M. "Toremifene citrate increases bone mineral density in men receiving androgen deprivation therapy for prostate cancer." Abstract # 149

Smith, M. "Toremifene significantly lowers total cholesterol, LDL, and triglycerides and raises HDL in men receiving androgen deprivation therapy for advanced prostate cancer." Abstract # 15

2007 Prostate Cancer Symposium
MedPage Today, 23 February 2007

Satraplatin

(Continued from page 3)

better," Dr. Kelly said.

Dr. Petrylak commented that satraplatin was "very well tolerated." The most common toxicities were myelosuppression (neutropenia, thrombocytopenia) and gastrointestinal effects (nausea, vomiting), but they were generally mild to moderate. Participants in this trial will continue follow-up to determine overall survival.

2007 Prostate Cancer Symposium
Medscape Medical News, 27 February 2007

Androgen Receptor Test

(Continued from page 2)

levels are an important feature in the predictive model, and that preliminary analyses have suggested that it may play a role in predicting response to hormone therapy.

2007 Prostate Cancer Symposium
Press release, 24 February 2007