INSIDE THIS ISSUE

Us TOO® PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

October 2005

US TOO FOUNDERS' FUND DONATIONS GROW

In honor of Us TOO's 15th anniversary, the Us TOO International Board of Directors established the Us TOO Founders' Fund to recognize the contributions and efforts the five prostate cancer patients who founded Us TOO. John DeBoer, Edward C. Kaps, John Moenck, Edward G. von Holst and Vincent Young were instrumental in forming Us TOO peer to peer education and support groups, and expanding them into the vast international network that we have become.

Since the announcement was made Father's Day, June 19, 2005, 155 men and women have responded whole-heartedly to support Us TOO's mission by contributing more than $10,000.00 to date. "We are so pleased with the response," says Tom Hiatt, chair of the Us TOO development committee.

"The purpose of this Fund is to enable Us TOO to launch specific projects which help prostate cancer patients, their families and support

(Continued on page 2)

FDA'S ODAC PANEL REJECTS ABBOTT'S XINLAY

In a hearing on September 15th, the Oncologic Drugs Advisory Committee, an independent review panel that makes recommendations to the FDA about cancer drugs, rejected an application for the approval of the experimental prostate cancer drug, atrasentan, commercially known as Xinlay, from Abbott Laboratories Inc.

If approved, Xinlay would have been the first new drug for advanced, hormone-refractory prostate cancer since Taxotere, approved in 2004. Taxotere was the first drug approved for hormone refractory prostate cancer that showed a survival benefit.

According to U.S. Food and Drug Administration staff, in a preliminary report released on Monday, Abbott did not provide clear evidence of effectiveness for the drug. Two studies of Xinlay failed to show the drug slowed progression of advanced prostate cancer. Abbott, however, said pooling data from the trials demonstrated

Xinlay delayed the disease's spread and reduced pain from the disease's spread to the bone.

In addition, Xinlay caused fluid retention and heart failure in studies, the FDA staff said in a review posted on its Web site. The report also said more people taking the drug had irregular heart rhythms, known as arrhythmias, than those given placebo.

"There are some serious cardiovascular safety issues observed in two large studies, the staff report said. It also noted that the drug "does not demonstrate any clear evidence of clinical efficacy."

Abbott had asked the FDA to approve Xinlay based on studies showing that while the drug didn't slow cancer in a significant way, it may have helped some patients.

The FDA had agreed to review the application based on other potential benefits, such as slowing the onset of bone pain and reducing the need for narcotic analgesics.

FDA News
14 and 15 September 2005

US TOO PUBLICATIONS

In addition to the *HotSheet*, Us TOO offers a FREE e-mail based service called *NEWS You Can Use* sponsored by sanofi-aventis, providing updates on the latest prostate cancer related news. To subscribe or link to the archives, simply visit the Us TOO website www.ustoo.org.

Items contained in Us TOO publications are obtained from various news sources and edited for inclusion. Where available, a point-of-contact is provided.

References to persons, companies, products or services are provided for information only and are not endorsements. Readers should conduct their own research into any person, company, product or service and consult with loved ones and personal physician before deciding on **any** course of action.

THE US TOO PROSTATE CANCER *HOTSHEET* IS MADE POSSIBLE BY A CHARITABLE CONTRIBUTION FROM

AstraZeneca

US TOO FOUNDERS' FUND DONATIONS GROW

(continued from page 1)

systems. In particularly, the Fund would support projects which the Board determines are critical to the prostate cancer populations that Us TOO serves," says Hiatt.

"The Fund would also be used to initiate important projects rapidly, while Us TOO seeks potential additional funding for long term support," explains Hiatt. "This would assure that Us TOO does not miss a target of opportunity, when "time is of the essence."

A donation envelope has been inserted into this issue of the *HotSheet*, so if you haven't already contributed to the Us TOO Founders' Fund, please consider donating yet this year.

For your convenience, you may also make a credit card donation online at < www.ustoo.org> – click on "Visit Our Store" to see the appropriate product listing. Thank you for your continued support!

DON'T FORGET ABOUT MATCHING DONATIONS

An easy way to increase the impact of your donation is to have your employer match it. Thousands of companies have Matching Gift Programs that will double, or even triple, individual tax-deductible contributions made by their employees.

Check with your personnel office to find out about your company's program. They will give you a matching gift form that you can fill out and send to us with your contribution.

PROSTATE CANCER AWARENESS WEEK IN REVIEW: PROSTATE CANCER CARE - PAST, PRESENT, AND FUTURE

On September 22, 2005, Us TOO teamed up HealthTalk®, for a live prostate cancer web-cast and teleconference patient education forum in honor of Us TOO's 15th anniversary. This was one of many events scheduled during Prostate Cancer Awareness Week 2005.

The program, **Prostate Cancer Care: Past, Present, and Future,** featured Thomas N. Kirk, Us TOO President and CEO, along with Jim Kiefert, Ed.D., Chairman of the Us TOO Board of Directors, with his wife Maureen Kiefert, of Us TOO's Caregivers & Families Initiative. Dr. James McKiernan, Prostate Cancer Specialist from Columbia University College of Physicians and Surgeons, provided expert commentary.

This call featured lively and timely discussions of the past and present progress made in prostate cancer care, new and promising treatments, and critical information about the role of support groups as well as companions and family support.

While many of you participated in this excellent webcast teleconference, some may have missed the live program. As a result, HealthTalk® has archived the call on their website and will be available for three months by visiting <http://www.healthtalk.com/ustoo>.

Some of you who participated in the call may also want to review the text and listen again to this valuable program. You can listen to the call as well as review the text of the discussion.

ANTIOXIDANT VITAMIN AND MINERAL SUPPLEMENTATION MAY HELP PREVENT PROSTATE CANCER

The use of antioxidant vitamin and mineral supplements is associated with a lower incidence of prostate cancer among men with normal prostate specific antigen (PSA) levels.

Dr. Francois Meyer from Laval University Cancer Research Center, Quebec City, colleagues assessed whether daily supplementation with antioxidant vitamins (vitamin C, vitamin E and beta-carotene) and minerals (selenium and zinc) reduced the occurrence of prostate cancer or influenced its biochemical markers.

More than 5000 men were randomized to the supplements or placebo. Biochemical marker data were available at baseline and median follow-up of about 9 years for 3616 men.

Supplementation was associated with a 48% reduction in the incidence of prostate cancer among men with a baseline PSA level below 3 ng/mL, the authors report in the August 20th International Journal of Cancer (Vol. 11, pp. 182-6, 2005)

In contrast, men with a baseline PSA level of 3 ng/mL or greater who took supplements experienced a 54% increase in the incidence of prostate cancer.

Baseline vitamin C levels showed a similar pattern, they also note.

Antioxidant vitamin and mineral supplementation had no clear impact on the levels of five biomarkers of prostate cancer,

"Our study results support the hypothesis that chemoprevention of prostate cancer can be achieved with antioxidant vitamins and minerals."

They recommend additional trials "to identify the best preventative agent or combination of agents and to determine which dosages are both safe and effective."

Reuters Health, 5 August 2005

ONGOING SURVEY RESEARCH PARTICIPANTS NEEDED

A doctoral research study is ongoing to explore how men from specific ethnic groups adjust to prostate cancer, report pain and seek healthcare information. The purpose of this study is to help nurses and doctors learn how to better care for patients with diverse ethnic backgrounds. This research study will include Japanese American and European American men with prostate cancer, who meet additional requirements.

The study requires the participant to sign a written informed consent, complete a five part written survey (usually taking between 30 – 60 minutes), and return the survey via mail (a pre-addressed envelope and postage is provided).

Approval for this research study has been obtained through New York University Committee on Activities Involving Human Subjects. If you are interested in learning more about this research study, please contact the investigator, Mildred Ortu Kowalski, RN, MPA. She can be reached by phone at (973) 452-0233, or by E-mail at m_ortu@usa.net.

Thank you!

PROTECTIVE EFFECTS OF BLACK TEA EXTRACT ON TESTOSTERONE INDUCED OXIDATIVE DAMAGE IN PROSTATE

Siddiqui IA[1], Raisuddin S,[2] and Shukla Y[1]

Cancer Letters 227:125-32, 2005

Since ancient times, antipyretic, anti-inflammatory, antimicrobial and antioxidative properties of tea have been recognized. Black tea (*Camellia sinensis*) contains a variety of polyphenolic ingredients including the theaflavins (TF), thearubigins (TG) and catechins. Components from black tea have been accounted to play an important role in scavenging free radicals generated by mutagens and carcinogens.

Androgens are the key factors in either the initiation or progression of prostate cancer (PCA) by inducing oxidative stress. In the present set of investigations, the antioxidative potential of black tea extract against androgen mediated oxidative stress in male Wistar rats has been studied.

Testosterone was given at a dose of 5 mg/kg b.w. subcutaneously, consecutively for 5 days. Prior to androgen administration, animals were kept on 0.5, 1.0 and 1.5% aqueous tea extract (ATE) as sole source of drinking fluid for 15 days. The prostate tissue was dissected out for biochemical analysis for antioxidant enzymes viz. catalase (CAT), superoxide dismutase (SOD), lipid peroxidation (LPO), glutathione-*s*-transferase (GST) and glutathione reductase (GR).

The results revealed that testosterone administration induced the oxidative stress in rat prostate, however, in 0.5, 1.0 and 1.5% ATE supplemented groups, a significant protective effect of black tea against testosterone induced oxidative injury was recorded. Hence, the study reveals that constituents present in black tea impart protection against androgen induced oxidative injury that may result in development of prostate cancer.

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PROTEIN SIGNALS AGGRESSIVE PROSTATE CANCER

Testing prostate tumor tissue for activated Stat5 protein can help identify men with an aggressive form of the cancer.

That's the conclusion of a study in the Aug. 15 issue of Clinical Cancer Research.

Researchers at the Lombardi Comprehensive Cancer Center at Georgetown University in Washington, D.C., analyzed prostate cancer tissue from 357 men and matched the Stat5 levels in those samples to the men's outcomes.

They found that the presence of Stat5 protein in the nucleus of prostate cancer cells was a significant predictor of when men would develop a recurrence of aggressive prostate cancer years after their initial treatment for the disease.

When activated, Stat5 signals cancer cells to grow and survive, the researchers said.

Testing for Stat5 levels in prostate cancer patients may help doctors better target treatment, the study authors said.

"Most patients diagnosed with prostate cancer have slow-growing tumors that don't need aggressive therapy, but doctors do not have a way to identify the few men whose cancer is potentially dangerous. The result is that many patients are over-treated," study principal investigator Dr. Marja Nevalainen, an assistant professor in the department of oncology, said in a prepared statement.

"If future studies with Stat5 continue to show that it can help in predicting disease outcome, then we can test tumor biopsy samples for Stat5 and tailor treatment accordingly," Nevalainen said.

HealthDay News, 19 August 2005

SCREENING SPARES MEN FROM ADVANCED PROSTATE CANCER

Among middle-aged and older men, those who have had PSA tests are less likely to be found to have prostate cancer that has spread to other sites in the body, Canadian researchers report.

Dr. Jacek A. Kopec of the University of British Columbia, Vancouver, told Reuters Health, "There was a 35 percent reduction in risk among those who were screened." Further, he added, "We observed a reduction in risk for both men under 60 years of age and those 60 years or greater, although the effect appears to be stronger in younger men."

Kopec and colleagues conducted a population-based study involving 236 cases of metastatic prostate cancer and compared them with 462 similar men who did not have metastatic prostate cancer, although they could have localized prostate cancer.

Based on the medical records, the rate of PSA screening was significantly lower in men with advanced prostate cancer than in the comparison group, the team reports in the August issue of the Journal of Urology.

In those between 45 and 59 years of age, screening reduced the odds of having metastatic cancer by 48 percent, and in men between 60 and 84 years old, by 33 percent.

Kopec noted that the value of PSA screening is debated, because it hasn't been shown to reduce mortality rates from prostate cancer. "We believe our study contributes to this debate in an important way," he said, "because it offers new evidence that screening with PSA can reduce the risk of death from prostate cancer -- the evidence is indirect as the outcome we looked at was metastatic cancer rather than death."

Reuters Health, 26 August 2005

PSA IN YOUNG ADULTHOOD MAY PREDICT PROSTATE CANCER

Levels of prostate specific antigen (PSA) in young men seem to foretell their likelihood of developing prostate cancer later in life, according to the results of a new study.

Dr. Alice S. Whittemore, of Stanford University School of Medicine, California, and colleagues assessed PSA levels from blood samples collected from a group of young black and white men between 1959 and 1966. The subjects, who were 34 years old on average at the time the samples were taken, were followed for several decades for prostate cancer.

The researchers report in the August 2005 issue of the Journal of Urology that prostate cancer risk increased with increasing PSA in black and white men.

"When the men were young, their PSA levels were well within the normal range, but the men with higher (though still normal) levels had higher risk," Whittemore explained.

Specifically, for men with the highest levels compared to those with the lowest, the chances of developing prostate cancer were 4.4-times higher for black men and 3.5-times higher for white men.

A direct biological reason could be that PSA in youth may increase in proportion to the number of premalignant or malignant cells in the prostate. Or, "PSA may itself contribute to neoplastic initiation or progression in the prostate," the researchers note.

"One might think that we should screen men at younger ages," Whittemore noted. "However, we still don't know if PSA screening saves lives," she said.

In addition, "Screening carries a psychological burden, not to mention the cost."

Reuters Health, 29 August 2005

NEWS AND VIEWS - EVOLUTION AND RESOLUTION OF SIDE EFFECTS FOLLOWING TREATMENT OF LOCALIZED PROSTATE CANCER

A recent study of prostate cancer survivors' long-term health-related quality-of-life (HRQOL) identified some important differences among men initially treated with radical prostatectomy (RP), 3-dimensional conformal radiotherapy (3-D RT), or brachytherapy (BT), and a control group without prostate cancer. With all three treatments yielding excellent survival, HRQOL figures prominently in the preferences of men with localized prostate cancer.

Investigators from the University of Michigan and Beth Israel-Deaconess Medical Centers studied HRQOL among men who had been treated for localized prostate cancer, with a median time since treatment of 6.2 years. Analyses were done to identify any differences associated with initial treatment, and to compare long-term HRQOL with earlier evaluations done at a median time from treatment of 2.6 years. Several prostate-cancer–specific domains of HRQOL were considered—urinary irritative, urinary incontinence, bowel, sexual, and hormonal/vitality.

The key findings, reported in the *Journal of Clinical Oncology* (Vol. 23, pp. 2772–80, 2005), relate to how the long-term side effects of various treatments develop and resolve over time.

"Perhaps our most novel and important finding is that disease-specific HRQOL continues to change and evolve among men treated with BT and 3-D RT, whereas RP HRQOL remains relatively stable between 2 and 6 years of median follow up," said first author David C. Miller, MD, Lecturer at the Michigan Urology Center, University of Michigan Medical Center.

At a median follow up of 6.2 years, men treated with RPhad HRQOL summary scores significantly lower than those of controls in the urinary incontinence and sexual domains; 3-D RT significantly diminished scores in the bowel and sexual domains; and BT had significant adverse impact on the urinary irritative, urinary incontinence, bowel, and sexual domains.

Compared with their responses 4 years earlier, men in the BT group reported a significant resolution in urinary irritative problems. During the same period, urinary continence became more problematic among men initially treated with 3-D RT or BT. Bowel side effects improved in the BT group. Sexual function declined among controls and among men treated with 3-D RT . None of the four groups reported any significant changes in the hormonal/vitality domain.

The item of "problem with pain or burning on urination" typifies trends in the urinary irritative domain. This problem was reported by 23% of survivors at 2.6 years after brachytherapy; 4 years later, this problem was reported by 10%. This problem was reported by no more than 3% of prostatectomy or conformal radiotherapy patients at both follow-up intervals.

During the same interval, "leakage of urine more than once a day" increased from 11% to 18% in the BT group. Corresponding values at 2.6 and 6.2 years were 17% and 16% for the RP patients, and 6% and 4% following 3-D RT .

As an example of bowel concerns, "problem with urgency to have a bowel movement" declined from 19% to 10% during this period for BT patients. In each time period, 14% of men treated with 3-D RT reported this problem; in the RP group, there was no substantial change in this side effect over time (3% and 5% at 2.6 and 6.2 years, respectively).

The percentage reporting "poor to no ability to have an erection" remained relatively unchanged over time following RP (62% and 65% at 2.6 and 6.2 years), but increased in the 3-D RT group (from 65% at 2.6 years to 75% at 6.2 years) and in the BT group (from 71% to 82%). The control (no prostate cancer) group also reported an increase in this item, from 19% to 29%. In comparing the prevalence of this problem, however, it should be noted that the median ages differed among the control (69.1 years), RP (67.2 years), 3-D RT (75.7 years), and BT (70.4 years) groups.

Although these results are generally consistent with those of previous studies, they provide a clearer view of likely outcomes than most earlier reports because the data are recent enough to reflect outcomes of modern technology for BT and 3-D RT, yet mature enough to be relevant over a follow up interval of interest to men facing these decisions.

"We believe that this study is useful because it is one of the first to use a validated instrument (EPIC) to measure long-term, patient-report HRQOL changes during the late survivorship phase following contemporary therapies for localized prostate cancer, including BT and 3-D RT," said Miller. "These observations highlight the need for corroborative multi-institutional, prospective studies that further characterize HRQOL evolution among long-term (>5 years) prostate cancer treatment survivors. Until such studies mature in coming years, the observed HRQOL changes described herein may provide clinicians and patients that choose a specific treatment with an estimation of their long-term HRQOL outcomes."

CA Cancer J Clin 55:269-270, 2005

PCA-HEALTHY COOKBOOK, CALENDAR RAISE AWARENESS AS WELL AS FUNDS FOR US TOO

2006 Calendar
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Twelve retirement community friends take it all off for a good cause. The calendar features nude-but-strategically-covered mature women in a light-hearted manner. Order your "Blue Ribbon Girls for Prostate Cancer" 2006 calendar today!

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Questions? Email blueribbongirls@aol.com

"BLUE RIBBON RECIPES FOR A HEALTHY PROSTATE – COOKING HEALTHY WITH JOHN DODSON"

John Dodson -
Gourmet chef and prostate cancer survivor

More information about both items can be found at:

http://www.ustoo.org/ProductInfo_NoPayPal.asp

John Dodson is a gourmet chef, and a prostate cancer survivor. Soon after his diagnosis in 1999, he joined a support group - the Prostate Cancer Support Group of Greater Kingsport, Tenn. (affiliated with Us TOO International) - and began learning about the importance of healthy diet for prostate health from Dr. Charles E. "Snuffy" Meyers.

He shares his love of cuisine in the form of a cookbook titled *Blue Ribbon Recipes for Prostate Health* - a collection of 170 of his favorite recipes adapted to promote prostate health. The cookbook includes recipes for appetizers & beverages, soups & salads, vegetables & side dishes, main dishes, breads & rolls, desserts, cookies & candy, and "This & That" miscellaneous items, all for only $15.50 each, shipping and handling included.

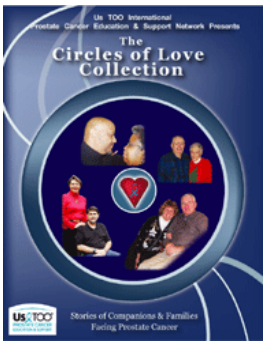
Checks or money orders only please (make out to "Prostate Cancer Support Group"). All proceeds benefit prostate cancer support group services. PLEASE WRITE Us TOO IN THE MEMO SECTION OF THE CHECK so a portion of your purchase can be directed to Us TOO International.

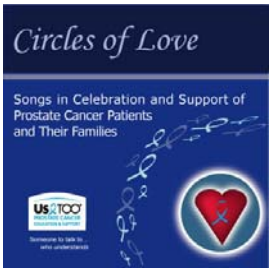
Mail your check, along with your name and complete mailing address to:

Prostate Cancer Support Group
Attn: John Dodson
1252 Catawba Street
Kingsport, TN 37660

Questions? Call 423-245-3234 or Email Kathryn_W_Visneski@wellmont.org

US TOO FEATURED RESOURCES — To order, visit www.ustoo.org





1). **NEW!** ***The Circles of Love Care Kit*** – $24.99 includes S+H
The challenges of the caregiver may not show up on a lab chart or test result, yet they are often equally painful and traumatic. Our new care kit is an excellent resource collection for friends and loved ones of those facing the battle against prostate cancer. Our care kit includes:

- ***The Circles of Love Collection: Stories of Companions and Families Facing Prostate Cancer***
  This new book, an Us TOO original publication, is a compilation of interviews with friends and loved ones of prostate cancer patients. These supportive and inspirational stories are meant to help others who are facing similar challenges. Also available separately for $17.00 includes S+H
- ***Circles of Love*** **Music CD** –This original collection of upbeat and inspirational songs was written to celebrate the love and support between the patient and his companions and family members. Contributing artists include Soozie Tyrell of the E Street Band, Alan Glass (who has written hits for Aretha Franklin, Earth, Wind & Fire, Kenny G, and more), Jerry Peters (whose song "Going In Circles" has been recorded by Luther Vandross, Isaac Hayes and Friends of Distinction), country artist Deborah Allen, and folk artist Kat Eggleston. 12 songs including pop, R&B, soul, country, folk and dance. Also available separately for $15.00 includes S+H.
- ***Intimacy with Impotence: The couples guide to better sex after prostate disease***
  This book, authored by Ralph and Barbara Alterowitz, is written for couples who have survived prostate cancer and whose normal sexual function has been disrupted. The authors bring a unique and personal perspective to the topics as they too live this experience. 220 pages.
- ***What You Need to Know about Prostate Cancer*** – from NIH and NCI
- ***"Life after Cancer Treatment" Resource and Referral Guide*** – excerpt from NCI

2). **Prostate Cancer Car Magnets "Know Your PSA"** — $5.00 each includes S+H

3). **Prostate Cancer Awareness & Us TOO's *STRIVE Initiative* Wristbands** — $1.00 each plus S+H

4). ***HotSheet*** **Subscriptions** – $35 for 12 issues
The Us TOO monthly newsletter is distributed FREE at all Us TOO Support Group Chapter meetings, and on www.ustoo.org. But what if you are unable to regularly attend chapter meetings, or don't have access to the Internet? Don't miss an issue—we can deliver it right to your home or office!

5). ***"What You Need To Know For Better Bone Health"*** – FREE Us TOO brochure

6). ***100 Questions & Answers About Prostate Cancer*** – $14.95 includes S+H, By Pamela Ellsworth, MD, John Heaney, MD, Cliff Gill

7). **Prostate Cancer Resource Kit** – $18.95 includes S+H
Included in this handy boxed kit:

- ***A Primer on Prostate Cancer*** - by Dr. Stephen Strum and Donna Pogliano
- **Know Your Options** – from Us TOO and the National Cancer Institute (NCI)
- **Prostate Cancer Treatment Guidelines For Patients** – from the National Comprehensive Cancer Network (NCCN) and the American Cancer Society
- **What You Should Know About Prostate Cancer** - from Prostate Cancer Research Institute (PCRI)
- **Prostate Cancer Resource Guide** - from the American Foundation for Urologic Disease (AFUD)
- **Us TOO / Phoenix 5 CD-ROM** - developed by Robert Young

8). **Understanding Prostate Cancer: A Patient's Resource Kit** – $7.50 includes S+H
Included in this handy boxed kit:

- ***Humanizing Prostate Cancer: A Physician-Patient Perspective*** by Roger E. Schultz, MD (Physician), and Alex W. Oliver (Patient)
- **Living With Prostate Cancer** — booklet
- **Know Your Options** – from Us TOO and the National Cancer Institute (NCI)
- **Living With Advanced Prostate Cancer video** - patient testimonials on Viadur

9). **Prostate Pointers Virtual Support Communities** – FREE at www.prostatepointers.org

10). **Us TOO Prostate Cancer *NEWS You Can Use*** – FREE e-News, subscribe at www.ustoo.org/Email_Subscription.asp

Proceeds from all items benefit Us TOO's FREE programs, support services and educational materials for prostate cancer patients and their families

DN-101 AND DOCETAXEL STUDY RESULTS SHOW PROMISE FOR ANDROGEN INDEPENDENT PROSTATE CANCER PATIENTS

Dr. Tomasz Beer of OHSU presented the efficacy and safety data from the ASCENT (**A**IPC **S**tudy of **C**alcitriol **EN**hancement of **T**axotere) Study at the recent Prostate Cancer Foundation Scientific Retreat held in Phoenix on September 29-October 1.

As reported at ASCO earlier this year the ASCENT study is a randomized, placebo controlled study of DN-101 (oral high dose pulse administration of calcitriol) and weekly docetaxel versus placebo and weekly docetaxel in 250 men living with androgen independent prostate cancer. The final analyses performed in March 2005 demonstrated that the ASCENT regimen of DN-101 and docetaxel favorably affected several measures of efficacy and activity as compared to placebo and docetaxel. Most significant was a survival benefit that was statistically and clinically significant indicating that the combination of DN-101 and docetaxel extended the survival by approximately 49%. There were also trends favoring DN-101 and docetaxel for complications of prostate cancer involvement of bone as determined by skeletal related events (SREs) and mortality as well as for PSA response rates (the primary endpoint), tumor response rates, and time to PSA response.

ASCENT also demonstrate unexpected favorable differences in the safety profiles for DN-101 and docetaxe as compared to placebo and docetaxel. Serious adverse events (primarily hospitalizations) were much less frequent (28% versus 41%) in the patients who received DN-101 instead of placebo.

Similarly the more severe adverse events (grade 3 and 4 on the NCI toxicity scales) were much less frequent in the patients who received DN-101 and docetaxel. Dr. Beer emphasized that these results were unanticipated and unexpected and as such they require confirmation in an additional clinical trial to establish whether or not DN-101 can improve the safety profiles of men with AIPC who are receiving weekly docetaxel. Despite these caveats, Dr. Beer indicated that the effects of DN-101 on the safety profiles of men with AIPC receiving docetaxel chemotherapy are very unusual and would be very important to patients assuming they are confirmed as they indicate that DN-101 will both improve the efficacy of chemotherapy while making it more tolerable and less toxic for the patients receiving treatment.

Dr. Beer stated that a large comparative clinical trial comparing the ASCENT regimen of DN-101 and weekly docetaxel to docetaxel administered on a every three weekly schedule (the approved schedule and dose for docetaxel for AIPC) has been planned and will be starting at the end of 2005.

The objectives of this large trial is to confirm and extend the observations from ASCENT in regard to the potential benefits of DN-101 on survival, SREs, and the safety profiles of men with AIPC receiving docetaxel chemotherapy.

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