Us TOO PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

November 2006

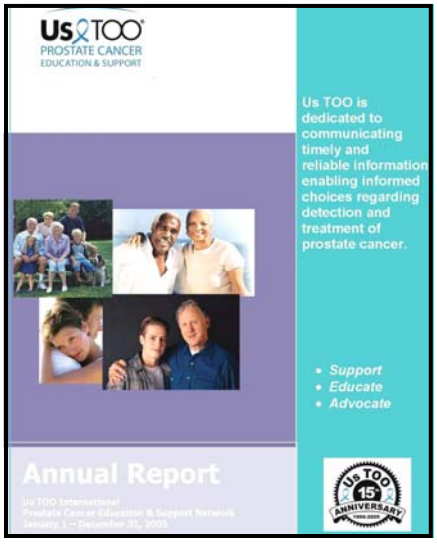
INSIDE THIS ISSUE

Us TOO Publishes 2005 Annual Report

Us TOO International recently published its Annual Report for 2005. Copies were sent to all Us TOO Chapters with the October HotSheet mailing. It can also be found on the Us TOO website, or by calling the Home Office for a copy.

"Last year was a milestone year for Us TOO – it was the first time we raised more than a million dollars in a year, and it was the first time we spent more than a million dollars in a year for program services," says Tom Kirk, President & CEO.

The two primary programs launched in 2005 were the education and support program for companions and families of prostate cancer patients, *Circles of Love*, and the complete redesign and expansion of the Us TOO website. After the new site was introduced, traffic jumped from approximately 50,000 hits per month to current levels of approximately 347,000 hits per month.



Year 2005 also brought in the new leadership team of Chairman of the Board, Jim Kiefert, and President & CEO, Tom Kirk. Their focus has been – and continues to be – on collaboration and mission, both internal and external to the network.

Last year also marked the organization's 15-year anniversary, and Us TOO's founders and founding partners are recognized. See the report for a complete review of highlights and financial status.

Focal Cryoablation Effective in Destroying Prostate Cancer

After 70 Months, 92.8 Percent of Patients Remained Disease Free, 88.9 Percent Retained Potency Following Targeted, Minimally Invasive Treatment

Endocare, Inc. (OTC Bulletin Board: ENDO - News), an innovative medical

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Good Long-Term Results for Intensity Modulated Radiation Therapy (IMRT)

Results from the largest study of men with prostate cancer treated with high-dose, IMRT show that the majority of patients remain alive with no evidence of disease after an average follow-up period of eight years.

Results from the largest study of men with prostate cancer treated with high-dose, intensity modulated radiation therapy (IMRT) show that the majority of patients remain alive with no evidence of disease after an average follow-up period of eight years.

The 561 prostate cancer patients treated with IMRT at Memorial Sloan-Kettering Cancer Center were classified into prognostic risk groups. After an average of eight years, 89 percent of the men in the favorable risk group were disease-free and none of the men in any group developed secondary cancers as a result of the radiation therapy.

This report, published in the October 2006 issue of The *Journal of Urology*, is the first description of long-term outcomes for prostate cancer patients using IMRT.

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US TOO INTERNATIONAL

has received Charity Navigator's highest rating for sound fiscal management. Less than a quarter of the charities in America receive this exceptional rating.

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US TOO PROSTATE CANCER EDUCATION & SUPPORT

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CIRCLES OF LOVE GOES TO SCHOOL

As students of all ages headed back to school this fall, so did the students at September's Us TOO University in Columbia, South Carolina. A group of nearly eighty support group leaders participated as students in nine courses making up a well rounded curriculum, including one session about Us TOO's **The Circles of Love** companion and family support tools. The session was called, *The Unseen Patient ~ Supporting Companions & Family Members Too*, facilitated by Maureen "Mo" Kiefert and Elizabeth Cabalka.

With the growing awareness of the far-reaching impact of prostate cancer beyond the patient, more support groups include spouses, companions, adult children and family members. Recent studies show the critical role supportive companions and family members can play in the lives of prostate cancer patients and survivors. Studies also show that this group needs support too.

As a result, support group leaders at Us TOO University were actively seeking tools to provide assist these "unseen patients."

In this session, participants had an opportunity to experience a few of Us TOO's excellent tools first hand.

Those attending the session listened as a story from the book The Circles of Love Collection was read aloud by a participant. A lively discussion then followed using the Circles of Love Discussion Guide. Stimulated by the compelling questions, the participants shared:

- From their own personal experiences with prostate cancer
- Ideas about using the materials in their own support groups.

Feedback indicates that chapter leaders will be turning to these valuable tools more and more in the future. Many participants commented on the shift in group dynamics by simply sitting in a circle and facing each other (a suggested used for the Circles of Love tools) as opposed to sitting in rows, disconnected from those around them. Others commented on the important applications they saw for their support groups, both large and small.

The Circles of Love and Us TOO University received a solid A+!

BONE LOSS RELATED TO HORMONE THERAPY-WHAT TO DO? (RTOG 0518)

The standard treatment for men with locally advanced prostate cancer is hormone therapy (LHRH agonist) combined with external beam radiation therapy. The data supporting this treatment is extensive and it shows a definite survival advantage for this approach over radiation therapy alone. Unfortunately, the long-term hormone therapy, that is necessary to prevent the spread or recurrence of prostate cancer, can affect bone health and, in some patients, cause bone demineralization, or osteoporosis. What should be done to prevent and /or treat potential bone demineralization for prostate cancer patients has not been well studied. We know that vitamin D and calcium are critical for good bone health, as is exercise, but, what else, if anything, can be done to help maintain good bone health? The Radiation Therapy Oncology Group (RTOG), a National Cancer Institute (NCI) funded national cooperative group, wants to answer this question. This past spring RTOG opened a clinical trial, RTOG 0518, to examine this problem. The study is open to men who have been treated for "high risk" prostate cancer with any form of radiation therapy (external beam or brachytherapy) and have received more than one year of LHRH hormone therapy. Eligible patients can also not have evidence of metastatic disease. All patients entered in the trial will be provided with vitamin D and calcium supplements. Half of the patients will also receive the drug Zometa®, a bisphosphonate that may improve bone strength. Patients on this trial are supplied with supplements of vitamin D and calcium daily and every three months they receive a 15 minute IV infusion of either Zometa® or a Placebo. All costs of the drug/Placebo are covered, as are the required x-rays of the spine. This study will answer the question of whether receiving a bisphosphonate is better for the maintenance of good bone health in this group of patients over vitamin D and calcium supplements alone. For more information please visit <www.rtog.org> or contact RTOG Headquarters at 800-227-5463 x 4189. The complete research protocol can be found at: <http://www.rtog.org/members/protocols/0518/0518.pdf>.

FOCAL CRYOABLATION

(Continued from page 1)

device company focused on the development of minimally invasive technologies for tissue and tumor ablation, announced today that a new study has demonstrated that specially targeted cryoablation, known as "focal cryoablation," may effectively destroy cancerous tumors in the prostate while preserving a patient's potency and continence. Focal cryoablation is an innovative and non-surgical type of cryoablation that uses the Endocare Cryocare Surgical System® to precisely target, freeze and destroy only cancerous tissue while sparing surrounding nerve structures and healthy tissue.

The study, published in the September issue of The Journal of Endourology, consisted of 31 men with a mean age of 63 who underwent the focal cryoablation procedure and whose disease was believed, through targeted and systematic biopsies, to be unilateral or confined to one sector of the prostate gland. At a mean follow-up of 70 months, 92.8 percent (26 of 28) remained biochemically disease-free and 96 percent (24 of 25) had no evidence of cancer on post-treatment biopsy. The one biopsy-positive patient had his prostate subsequently treated with full gland cryoablation and currently remains biochemically disease-free. Follow-up for the study consisted of PSA measurement every three months for one year and every six months thereafter, with biopsies at six months, one year, two years, five years and following any three consecutive PSA rises.

Potency was completely maintained in 41.8 percent (13 of 27) of the patients and 40.7 percent of the others (11 of 27) were potent with erectile dysfunction drugs, for a total potency preservation rate of 88.9 percent. The patients experienced no other complications, such as incontinence. Potency was determined with a patient questionnaire, and only disease stage, not preoperative PSA or tumor differentiation was considered a potential contraindication.

"Today, we are much more vigilant in diagnosing prostate cancer and as a result we are identifying the disease earlier and in younger men," said Duke K. Bahn, M.D., the lead investigator of the study and director of the Prostate Institute of America based at Community Memorial Hospital in Ventura, California. "Unfortunately, until now, this growing population has had few options: either doing nothing, which we often call 'watchful waiting,' or choosing one of several fairly radical procedures, including prostatectomy and radiation treatment. The outcomes we are seeing from focal cryoablation demonstrate that many of these patients now have a new option that not only is minimally invasive, but it destroys the cancer, maintains their potency and quality of life, and can even be performed as an outpatient procedure in many cases."

Endocare's Chairman, President and Chief Executive Officer, Craig T. Davenport, noted that the new data demonstrate that it is possible for certain prostate cancer patients to go on to lead normal and sexually active lives following focal cryoablation, which is a potential option for men whose tumor is confined to only a portion of the prostate.

"Studies continue to demonstrate what we have been hearing first-hand from a variety of urologists -- that focal cryoablation can destroy the disease while preserving the surrounding healthy tissue that is critical to normal sexual function," Davenport said. "This is very significant news for any man diagnosed with prostate cancer who is concerned about surgery or the side effects of radiation because it represents a new, minimally invasive, non-surgical option and does not include many of the debilitating side effects, such as impotence and incontinence, which can occur with more aggressive therapies. We believe that focal cryoablation fills a void in the treatment options available to patients and signals a tremendous advance in the treatment of prostate cancer."

About Endocare

Endocare, Inc. <www.endocare.com> is an innovative medical device company focused on the development of minimally invasive technologies for tissue and tumor ablation. Endocare has initially concentrated on developing technologies for the treatment of prostate cancer and believes that its proprietary technologies have applications for the ablation of tumors in the kidney, lung and liver.

HIGH-DOSE IMRT RESULTS

(Continued from page 1)

"Our results suggest that IMRT should be the treatment of choice for delivering high-dose, external beam radiotherapy for patients with localized prostate cancer," said Dr. Michael J. Zelefsky, Chief of the Brachytherapy Service at Memorial Sloan-Kettering. "We were able to show long-term safety and long-term efficacy in a very diverse group of prostate cancer patients that we followed many for as long as ten years. Despite the fact that some patients had an aggressive form of their disease with high Gleason scores and PSA (prostate specific antigen) levels, the overwhelming majority of patients had good tumor control with neither recurrence of their original cancer nor development of second cancers, which one might have expected from the high doses of radiation," he added.

Pre-treatment diagnostic evaluations were performed for all of the patients to better define their clinically localized prostate cancer. They were classified into prognostic risk groups as defined by the National Comprehensive Cancer Network guidelines <http://www.nccn.org/>. These are based on clinical characteristics including age, T stage, Gleason score, PSA level, and pre-treatment with neoadjuvant androgen deprivation.

Between April 1996 and January 2000, 561 patients with a median age of 68 (ranging from 46 to 86 years old) were treated with IMRT, an improved form of three-dimensional conformal radiation therapy (3D-CRT), also used in radiotherapy. IMRT uses enhanced planning treatment software that more precisely targets the prostate, allowing the beam of radiation to deliver a high dose (81 Gy) to the tumor target while sparing the adjacent bladder and rectum from exposure to the higher amounts of radiation.

Perhaps because of this, the eight-year results show urinary continence was maintained for all patients, and only 1.6 percent of the five hundred sixty-one

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NCI CLINICAL TRIALS AT THE NIH CLINICAL CENTER

A Phase II Study of Bay 43-9006 (Sorafenib) in Metastatic, Androgen-Independent Prostate Cancer

NCI-04-C-0262

As you may know, the National Cancer Institute (NCI) is a component of the National Institutes of Health (NIH), and the federal government's main agency for cancer research and training in the United States.

But did you know that an increasing number of prostate cancer clinical trials are being conducted by the Center for Cancer Research (CCR) at the NIH Clinical Center in Bethesda, Md.? The following is just a small sample of the kind of work being done by this world-class team of principal investigators and research staff.

The GU/GYN Clinical Research Unit at NCI has been developing novel therapeutic strategies for the treatment of adenocarcinoma of the prostate. One of their current projects focuses on translational clinical trials – small studies of therapies emerging from the laboratory – for the treatment of prostate cancer.

According to Dr. William Dahut, "Sorafenib is a multi targeted tyrosine kinase inhibitor active against targets important in prostate cancer tumorgenesis. This trial in patients with metastatic disease which has progressed after hormonal therapy and chemotherapy hopefully will lead to tumor regression in this advanced patient population."

Many of the GU/GYN Clinical Research Unit's trials involve trials for patients with androgen independent and metastatic prostate cancer. Currently four trials are involved in the active treatment of patients.

A Pilot Study of Image-Guided Prostate and Pelvic Nodal Irradiation with Intensity Modulated Radiation Therapy (IMRT)

NCI-05-C-0241

The Radiation Oncology Molecular Imaging Section at NCI is involved with a number of different research protocols, many of which share the common question: Can outcomes for patients be improved by individualizing therapy?

The answer may come, in part, from a low-risk and high-risk (for lymph node involvement) radiation therapy trial. Dr. Anurag Singh explains, "This trial applies a new technology called intensity modulated radiation therapy (IMRT) to treat lymph nodes in patients with a high risk (greater than 10%) of prostate cancer in the lymph nodes. IMRT is more precise than standard radiation treatment.

Therefore, IMRT can treat more of the lymph nodes at risk while treating less normal tissue. This has the potential to improve survival while actually decreasing side effects. In the second part of this study, after the first ten patients, more radiation doses to the lymph nodes will be given. This has the potential to improve survival because higher doses may be more effective at curing disease in the lymph nodes."

FINDING PROSTATE CANCER TRIALS AT NCI

The National Cancer Institute (NCI), part of the National Institutes of Health (NIH), conducts more than 150 clinical trials at the NIH Clinical Center in Bethesda, Md. NCI is currently conducting clinical trials for patients with prostate cancer.

There is no charge for medical care received at the NIH Clinical Center. Study participants will be responsible for travel costs for their initial screening visits. Once participants are enrolled in a trial, NCI will pay for the transportation costs for all subsequent trial-related visits for participants who do not live in the local area. In addition, these participants will receive a small per diem for food and lodging expenses if they are being treated as outpatients.

A current listing of NCI's prostate cancer clinical trials, including a summary of eligibility criteria, treatment plan, and information on how to contact the principal investigators and their staff directly, is available online at <http://bethesdatrials.cancer.gov/prostate>. Assistance in finding a trial is also available at 888-624-1937.

A Phase I Feasibility Study of an Intraprostatic Prostate-Specific Antigen-Based Vaccine in Patients with Prostate Cancer with Local Failure after Radiation Therapy or Clinical Progression on Androgen-Deprivation Therapy in the Absence of Local Definitive Therapy

NCI-05-C-0017

The Laboratory of Tumor Immunology and Biology focuses on the clinical translation of new immunotherapeutic strategies—the treatment of disease by inducing or enhancing the body's immune response.

The Staff is currently conducting six vaccine-based trials for patients with metastatic carcinoma and advanced prostate cancer. Dr. James Gulley remarked that "Vaccine therapy for prostate cancer is a novel alternative that has been increasingly investigated in recent years. Because the prostate is not an essentially organ, use of vaccines containing epitopes specific to the normal or cancerous prostate, such as prostate-specific antigen (PSA), constitutes a rational approach for vaccine development." This trial utilizes a unique approach by injecting the vaccine directly into the prostate tumor in a manner designed to generate an optimal immune recognition and attack of the tumor. Early clinical data suggest that this is well tolerated and has been associated with decreases in PSA.

Doc Moyad's What Works & What is Worthless Column

Mark A. Moyad, MD, MPH
University of Michigan Medical Center-Dept of Urology
Phone: 734-936-6804

I have a "friend" that needs to quit smoking, is there anything new and legal that can help him to quit besides the usual several soft blows to his head from me while I repeatedly yell "quit smoking you dummy because I want you to live a long life?!"

It is time to be a bit more sensitive here because most of us have been there. It is simply really hard to stop smoking unless you are a chimney (I am on fire here with the jokes and no pun intended again)! Smoking is not just associated with lung cancer, but has also been associated with a worse prognosis after diagnosis and treatment from numerous cancers including prostate cancer. There are lots of options available today, but their success rates are minimal at best and there has been nothing novel in a long time.

However, a new and potentially effective pill that may help smokers quit smoking in a short period of time is just hitting the market. The FDA just approved the prescription drug Chantix® (also known as varenicline tartrate, which is from Pfizer, Inc., New York) tablets to help smokers quit smoking. The active compound in Chantix® may work in a unique way to help smokers quit. The drug acts in areas in the brain impacted by nicotine, and it may help smokers quit by providing some effects similar to nicotine, which helps to reduce symptoms of nicotine withdrawal. Chantix® also seems to block the impact of nicotine on the brain if a person starts to smoke again. In other words, it helps to reduce cravings and withdrawal and seems to simply reduce the pleasure of using nicotine if someone still smokes or begins to smoke again. It is difficult to imagine that smoking is the most preventable cause of death in the United States.

Quitting smoking would be the most significant cancer prevention achievement in our lifetime if everyone just quit tomorrow. It is even harder to imagine that smoking is responsible for about one third of the cancer deaths around the world! An estimated 45 million adults in the U.S. smoke and this is only part of the problem because effective methods to quit smoking are just not easy to find.

Chantix® was tested in six clinical trials, which included almost 3,700 chronic cigarette smokers who were treated with this drug. Smokers in these clinical trials were averaging 21 cigarettes a day for about 25 years. Chantix® was more successful in several of the clinical trials than even one of our gold standard medications Zyban® (also known as bupropion). The approved amount of time patients should take the drug is for 12 weeks, and patients that are successful may continue taking the drug for another 12 weeks to increase the likelihood that they will not smoke long-term.

This is what I like about the drug—the short period of time patients need to be treated. In clinical trials, the most common side effects of the drug were nausea, headache, vomiting, flatulence (gas), difficulty sleeping, abnormal dreams, and a change in taste perception. A final piece of advice-if you want to stop smoking by gradually reducing nicotine intake than wait till you have reduced your intake by about 50% before you use any smoking cessation pill or device. This will make it easier for any drug/patch/pill to work effectively.

Michigan Football Rules!!! (Aka "is number 1" for those that do not understand my lingo).

Reference:

U.S. Food and Drug Administration. FDA News. FDA approves novel medication for smoking cessation. P06-67. 2006. http://www.fda.gov/bbs/topics/NEWS/2006/NEW01370.html

Note: Dr. Moyad can also be emailed at <moyad@umich.edu>. Please always include your phone number in the email. Dr. Moyad is also the editor-in-chief of the new medical journal for health care professionals & patients from Elsevier called "Seminars in Preventive & Alternative Medicine" <www.elsevier.com>.

To reach Dr. Moyad, locate this journal on the Internet and just type in "Moyad" or call (800) 654-2452 or outside the U.S./Canada call (407) 345-4000.

SPECTRUM ANNOUNCES RESULTS FROM TRIAL OF PROSTATE CANCER DRUG

Spectrum Pharmaceuticals announced positive results from the Phase III satraplatin registrational trial known as SPARC (Satraplatin and Prednisone Against Refractory Cancer).

The trial is evaluating satraplatin, the first orally available platinum-based chemotherapy in advanced clinical development, plus prednisone versus placebo plus prednisone as a second-line treatment in 950 patients with hormone-refractory prostate cancer.

The study data show that the results for progression-free survival (PFS) are highly statistically significant using the protocol-specified log-rank test. PFS is the primary endpoint for submission for accelerated approval in the U.S. and will also serve as the primary basis for a marketing authorization application in Europe.

Patients in the SPARC trial who received satraplatin plus prednisone had a 40 percent reduction in the risk of progression compared with patients who received prednisone plus placebo. The type of prior chemotherapy did not affect the improvement in PFS in the satraplatin arm; in particular, the improvement was seen equally for patients who had received prior Taxotere (docetaxel) as well as those who received other types of chemotherapy treatments.

An independent expert review committee of medical oncologists and radiologists adjudicated all disease progression events. The majority of progression events were based on radiological progressions and pain progressions.

The company expects to submit a new drug application to the FDA by the end of the year, and the European marketing application will be filed in the first half of 2007. Satraplatin has been granted fast-track designation from the FDA.

FDA News, 26 September 2006

HIGH-DOSE IMRT RESULTS

(Continued from page 3)

patients experienced rectal bleeding.

The high-dose radiotherapy was curative for the majority of the patients in all three prognostic risk groups, with 89 percent of the favorable, 78 percent of the intermediate, and 67 percent of the unfavorable group alive after an average period of eight years. Of those men who were potent prior to IMRT, erectile dysfunction developed in 49 percent.

“This study confirms that we can improve patients’ quality of life by reducing the side effects of radiotherapy while maintaining disease-free survival,” said Dr. Zelefsky. “However, there is still room for improvement. We are incorporating image-guided approaches that may continue the excellent tumor control but further limit the area we are irradiating and reduce side-effects."

The study’s co-authors are Heather Chan, Margie Hunt, Yoshiya Yamada, MD, Alison M. Shippy, and Howard Amols, PhD, of Memorial Sloan-Kettering.

Memorial Sloan-Kettering Cancer Center is the world’s oldest and largest institution devoted to prevention, patient care, research, and education in cancer. Our scientists and clinicians generate innovative approaches to better understand, diagnose, and treat cancer. Our specialists are leaders in biomedical research, and in translating the latest research to advance the standard of cancer care worldwide.

Memorial Sloan-Kettering Cancer Center 27 September 2006

NEW LAW ALLOWS DRUG IMPORTATION

President Bush signed legislation on October 4, 2006 legalizing limited importation of prescription drugs from Canada, but a policy reversal by a federal agency could lead to even broader use of the practice.

Bush signed the fiscal 2007 Homeland Security Appropriations bill, which includes a provision prohibiting federal officials from stopping individuals from personally transporting prescription drugs across the Canadian border. The provision only applies to a "personal-use quantity," defined as less than a 90-day supply.

The move brought immediate criticism from the pharmaceutical industry. This new law is the "first step down a dark and dangerous road," leading to more counterfeit drugs entering the country, PhRMA Senior Vice President Ken Johnson said.

Meanwhile, the U.S. Customs and Border Protection (CBP) has gone a step further, deciding that it will no longer seize prescription drug shipments beginning Oct. 9, the agency said in an Oct. 2 email. Instead the CBP will refer these shipments to the FDA for action, although it was not clear in the announcement what effect this would have on shipments.

The CBP reviewed its policy and determined a change was necessary, an agency spokeswoman said. Under the new policy, the CBP will only act if there is evidence that a drug is counterfeit. The agency will then send the product to the FDA for a final decision.

This represents broader importation than that allowed in the appropriations language. The bill only allows citizens to carry drugs with them across the border, while the CBP decision covers mailed shipments as well.

"This is a huge victory," Sen. Bill Nelson (D-Fla.) said in an Oct. 3 release. Nelson, who had been challenging the CBP seizure policy, said that more than 40,000 people have had their prescriptions seized since the agency first implemented this policy last November. "Senator Nelson believes the change in policy was due to the pressure exerted by the senator and the American public," a Nelson staffer added.

Nelson had criticized the policy and sought a congressional investigation. Nelson will continue trying to get a congressional investigation to determine why the government began seizing these shipments in the first place, the staffer added.

Drug Industry Daily, 5 October 2006

GLOUCESTER PRESENTS UPDATE ON PHASE II TRIAL IN METASTATIC HORMONE REFRACTORY PROSTATE CANCER AT THE 31ST ESMO CONGRESS

Interim data show single agent activity reported in metastatic hormone refractory prostate cancer.

Gloucester Pharmaceuticals, Inc., a privately held cancer therapeutics development company, today reported that an update on an ongoing phase II clinical study investigating the use of

(Continued on page 8)

HORMONE THERAPY FOR PROSTATE CANCER LINKED TO DIABETES AND HEART DISEASE

Androgen-deprivation therapy for prostate cancer may increase the risk for diabetes and heart disease, according to a study published yesterday in the *Journal of Clinical Oncology*.

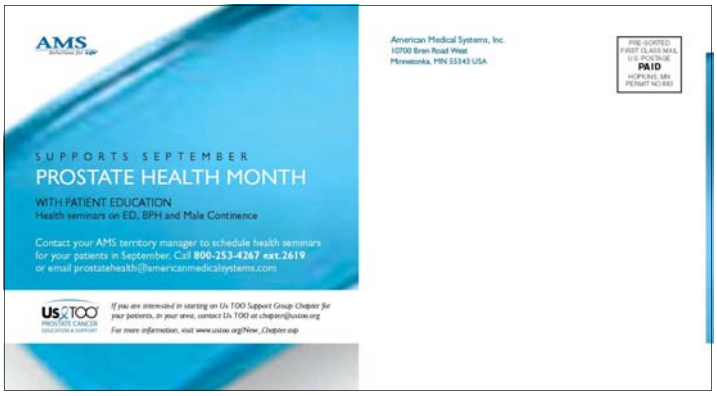
The observational study identified 73,196 Medicare enrollees diagnosed with locoregional prostate cancer and studied them at a median of 4.55 years after diagnosis. Men who took gonadotropin-releasing hormone (GnRH) agonists had hazard ratios of 1.44 for incident diabetes, 1.16 for incident coronary heart disease, 1.11 for myocardial infarction, and 1.16 for sudden cardiac death, compared with men who didn't take GnRH agonists, after adjustment for numerous socioeconomic and medical variables. Men treated with orchiectomy had an adjusted HR of 1.34 for incident diabetes, but no increased risk for coronary heart disease, MI, or sudden cardiac death.

Given the increasing use of hormone therapy for prostate cancer, the authors urged physicians to weigh its benefits against potential increased risks for diabetes and heart disease.

J Clin Oncol 24:4448-56, 2006

SUPPORTING US TOO INTERNATIONAL & PROSTATE CANCER AWARENESS

During September—Prostate Cancer Awareness Month, Us TOO was excited and so appreciative of all the chapters and corporate supporters who included Us TOO International in their national, regional or local awareness campaigns and events. If you had an event you'd like to tell us about, please send information and/or pictures to Pam Barrett, pam@ustoo.org. Thanks for your good work in helping spread the word about the needs of prostate cancer patients and their families.



American Medical Systems encourages the development of new Us TOO support group chapters on their Prostate Health Month postcard (front and back of postcard shown above).

(Above) Mike Jones and Chris Canales promote a screening event and hot rod show in Austin, TX.

(Below) Novacea presents Bob Scruggs of the Us TOO Silicon Valley Chapter with the Stanford game ball.

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

ARNIE'S ARMY BATTLES PROSTATE CANCER

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

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

GLOUCESTER'S NEW DRUG

(Continued from page 6)

the Company's lead product candidate, romidepsin (depsipeptide), in patients with metastatic hormone refractory prostate cancer (HRPC) was presented at the 31st European Society of Medical Oncology (ESMO) Congress being held in Istanbul, Turkey. The update was presented by Dr. Rhoda Molife, MRCP, MSc, MD, a Clinical Research Fellow in the Drug Development Unit of the Royal Marsden NHS Foundation Trust and The Institute of Cancer Research, London, UK.

Dr. Molife reported on interim data from 31 patients enrolled in the ongoing study. Of the 22 patients currently evaluable for radiological response, one patient achieved a partial response and two patients achieved stable disease for ≥ 6 months. An additional seven patients have shown evidence of disease stabilization for less than six months. Of the 27 patients currently evaluable for Prostate Specific Antigen (PSA) response, two patients achieved a partial response of >50% decrease in PSA for six months or greater and one patient had a 40% drop in PSA for five months. The adverse events seen in this trial to date were manageable with the most common being nausea, fatigue, vomiting and anorexia.

"The interim results of this study suggest that romidepsin, as a single agent, has clinically relevant activity in hormone refractory prostate cancer," stated Dr Molife. "These results are consistent with those reported earlier this year and we are continuing to enroll patients in the study with a goal of 25 patients evaluable for radiologic response," she concluded.

About Romidepsin (Depsipeptide)

In July 2006 the International Nonproprietary Names (INN) body of the World Health Organization (WHO) and the United States Adopted Names (USAN) Council approved the nonproprietary (generic) name romidepsin for depsipeptide (FK228). Romidepsin is a novel agent in a new class of anticancer drugs known as histone deacetylase inhibitors. The Company is conducting a pivotal study of Romidepsin for patients with cutaneous T-cell lymphoma (CTCL). Interim data for this trial, presented at this year's

American Society of Clinical Oncology meeting included 40 patients enrolled and 28 evaluable patients. The overall response rate reported was 36% (10/28) with 7% of patients achieving a complete response. The most common adverse events seen in this trial were nausea (52%), fatigue (33%) and vomiting (26%). This study is currently accruing patients.

Romidepsin has received both Fast Track and Orphan Drug Designation by the Food and Drug Administration (FDA), and Orphan Drug Designation from the European Agency for the Evaluation of Medicinal Products (EMEA). Romidepsin is also in clinical trials as a single agent and in combination with other cancer regimens for a variety of other hematologic malignancies, including peripheral T-cell lymphoma and multiple myeloma as well as solid tumors, including pancreatic cancer. The Company or the National Cancer institute (NCI), under a Cooperative Research and Development Agreement (CRADA) with the Company is conducting these trials and others.

Gloucester Pharmaceuticals, Inc. is a privately held, venture-backed company that develops and commercializes innovative products for treating cancer patients. Gloucester is headquartered in Cambridge, MA. For more information on Gloucester and our clinical development program visit our website at <www.gloucesterpharma.com> or call (888) GPI-CTCL [(888) 474-2825].

US TOO INTERNATIONAL: OUR MISSION

Communicate timely, personalized and reliable information enabling informed choices regarding detection and treatment of prostate cancer.

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Us TOO PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

SPECIAL BURNING ISSUES SUPPLEMENT

NOVEMBER 2006

THIS SUPPLEMENT TO THE *US TOO PROSTATE CANCER HOT SHEET* WAS MADE POSSIBLE BY CHARITABLE CONTRIBUTIONS FROM PEOPLE LIKE YOU

US TOO CELEBRATES PROSTATE CANCER AWARENESS ACTIVITIES

US TOO UNIVERSITY 2006 - COLUMBIA, SOUTH CAROLINA

Learn. Laugh. Lead.

Notebooks, book bags, pencils and pens. . .

September saw countless students of all ages heading back to school. Us TOO International support group leaders were no exception. Nearly eighty motivated support group leaders gathered in Columbia, South Carolina, September 29-30 for a two-day educational event called **Us TOO University**. This capped off an active September and Prostate Cancer Awareness Month.

This was the first event of its kind, further signifying Us TOO International's unwavering commitment to the education and support of those on the front line of prostate cancer – Us TOO's many volunteer support group leaders – as well as for patients and their family members affected by the disease. In keeping with Us TOO University's motto, ***Learn. Laugh. Lead.***, participants were provided with timely and useful information, they had a terrific time, and can now return home better prepared to confidently **lead**.

It is no secret that the prostate cancer community faces unprecedented growth. Us TOO University was designed to equip Us TOO's support group network for **today and the future.** The "Us TOO U" event really featured two events in one: the full-day training workshop for volunteer chapter support group leaders held on Saturday, and – on Friday evening – an educational symposium with vendor exhibits.

The *Friday Night Forum* portion of the 2-day program featured sessions on the latest information on treatment options, presented by leading local physicians from a variety of disciplines. The symposium was opened up to the entire local community, and prostate cancer patients and their spouses were invited to attend in addition to the volunteer training workshop students.

The evening started with general sessions on surgery, radiation, cryotherapy and chemotherapy treatment op-

(Continued on page 2)

The first graduating class of the Us TOO University 2006! Congratulations to the 78 volunteer chapter leaders who joined us!

SUCCESS IN CHICAGO—A TEAM'S TALE

The Second Annual Greater Chicago Prostate Cancer Run, Walk 'n Roll had a quite a different look in its sophomore year, with new faces doing their part in the fight against prostate cancer. Among these faces, a few stand out, including a platoon of warriors, a few pals, and a whole bunch of crewmembers. These three groups refer to some of the more successful "TEAMS" that participated in the Chicago Run, Walk 'n Roll. These three small groups of coworkers, friends, and family members combined to raise more than $6,000 that will help Us TOO International's efforts to support and educate the thousands of people touched by prostate cancer yearly.

The Don Johnson Prostate Warriors TEAM was created by the Don Johnson Chapter Leader, Russ Gould with the help of the Us TOO Staff in tribute of the founder of one of the earliest Us TOO chapter leaders. Simply by sending out a mailing to his chapter, as well as mentioning it at his chapter's meetings, Russ was able to encourage this chapter to raise almost $2,000.

Keeping up with these warriors was a motivated mom with a great idea. A local Chicago elementary school teacher, Pat Reed, started the Pat's Pals TEAM. After inviting some of her friends and family to join her on September 10th to take part in the

Example of a TEAMraiser fundraising webpage to encourage donations to walkers and runners

GREATER CHICAGO RUN, WALK 'n ROLL PROSTATE CANCER

walk, she decided she wanted to do more. She concluded after some thought to have her 800 students have a fundraiser to raise money for her team, Pat's Pals. Each student paid $1 to be out of uniform on the Friday before the walk, and in one day Pat raised $885 before the three o'clock bell! With the help of her other teammates, Pat and her Pals raised $2,100.

Not to be outdone, Coach's Crew put together a group that no one would forget. Five siblings, Judy, JoAnne, Wally Jr., Jeff, and Jim, put coach's Crew together in loving memory of their parents, Walter and Helen. Drawing inspiration from their late parents, the members of Coach's Crew; named after their father's devotion and work with youth athletics, worked together to raise over $2,100 to support the efforts of Us TOO International. They also showed their love of sports by showing up to the Sunday Walk fitted in Chicago Bears jerseys and sweatshirts; supporting their dad's team, who just so happened to trounce their rivals from Green Bay that day, 26-0.

Among these three extraordinary teams were numerous other groups of coworkers, friends, and family, who worked together to raise more than $46,000 for the Greater Chicago Prostate Cancer, Run, Walk 'n Roll. Forming teams on the walk's website, <www.prostatecancerrunwalknroll.org> individuals told their stories, pictures, and emails, all in the effort of helping the thousands of men and their families touched by prostate cancer every year.

Thanks to the work of teams like *Jim's Jaywalkers, Ted's Troops, Dr. G!, Pam's Pink Flower Power Rangers, "TNT"*, and the *Irish Brigade*, the Second Annual Greater Chicago Prostate Cancer Run, Walk 'n Roll was successful and provided Us TOO International with a strong foundation to improve on this success with more corporate teams in next year's Chicago event as well as this year's Houston event. Visit <www.ustoo.org> to access both of these events.

All of the previously mentioned teams can be viewed there as well so check them out for yourself and find out how you can help get a team event in your area.

US TOO UNIVERSITY

(Continued from page 1)

tions and followed with breakout sessions on each topic for further discussions. The session on incontinence and impotence solutions was extremely well attended. This evening event also featured ten exhibitors and delicious prostate-healthy refreshments!

The volunteer training workshop held on Saturday featured a wide variety of topics to give support group leaders the tools and information to move confidently and successfully into the future.

The curriculum featured nine diverse sessions:

- Reaching out and growing your chapter
- Mission critical: Supporting the newly diagnosed
- From cure to comfort: Supporting those facing end-of-life issues
- Grass roots advocacy: Every voice counts
- Recognizing and supporting emotionally challenged individuals
- Safe and effective chapter management
- What now? Support those with advanced disease
- The unseen patient: Supporting companions and family members
- Planning for the future of your chapter.

In attendance were men and women, young and young-at-heart, medical professionals, and lay people too. The sessions:

- Touched on a wide variety of topics

- Were extremely well-received
- Prompted lively discussion amongst participants

Not only did support group leaders learn from the many presenters, they actively learned from each other as well.

Us TOO University was made possible through the generous support of our sponsors:

Special thanks to our Platinum Program Supporter — sanofi-aventis

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Special thanks to Roland Young, Us TOO Senior Volunteer Regional Director, for all his hard work in making the first-ever Us TOO University program such a success… and so memorable with the Marine Color Guard and the 20-member choir!

Watch for information about future Us TOO University programs hosted in different locations around the United States! You don't want to miss it!

LIVING (AND EATING) WELL AT US TOO UNIVERSITY

Not only were there terrific informative educational sessions at Us TOO University, but the food was excellent as well. Most importantly, special attention was given to the menu to create delicious, nutritious, prostate healthy meals. Terri Gibbons (Us TOO staff) and Chef Robert of the Clarion Town House Hotel created abundant, stunning, appetizing, and visually inviting meals from the time participants arrived to the time they departed.

One participant said it well, "Not only did you nourish our minds with this terrific abundant information but you nourished our bodies as well with tasty, health-conscious meals each day. Thank you for attending to all the details."

Us TOO U presenters receive a special thank you, (standing) L to R: Elizabeth Brown, Gary Skramstad, Elizabeth Cabalka, Don Lynam, Mo Kiefert, Russ Gould, Jim Kiefert, Bill Palos, Ron Witherspoon, (kneeling): Tom Kirk

L to R: Us TOO U presenter Ron Witherspoon, student Fred Gersh, Us TOO Chapters Program Director Karen Bacher, and Us TOO Senior Volunteer Regional Director Roland Young enjoying the post-graduation festivities

Lew Musgrove (right), Us TOO Senior Volunteer Regional Director and Past Board Chair, leads the group in selecting healthy, nutritious and tasty menu options

US TOO INTERNATIONAL IS GROWING, MOVING AND CHANGING

By Tom Kirk, President & CEO, Us TOO International

It is no secret that we find ourselves in exciting, challenging and important times. As the prostate cancer community is rapidly growing, moving and changing, so is Us TOO International. We are leading the efforts to raise awareness, to educate and to support a population that previously spoke of prostate cancer only in whispers. Our foundation is firm, and we must continue to step up, speak out, and be heard.

Recent Us TOO events around the country, as well as numerous activities in the network, reflect a shift in awareness about prostate cancer. Communities are coming together to raise funds and awareness. Educational tools and events are helping to strengthen the support network - the very backbone if this organization. The reach of Us TOO's support efforts is expanding to new communities, demographics, and previously underserved populations. The foundation is firm and the time is now.

Prostate cancer is no longer spoken of only in low tones. Just as breast cancer is now discussed openly and support is readily available, we follow their example of raising awareness to critical mass and building support, always in a spirit of collaboration and partnership inside and outside the Us TOO network.

While we are profiling here only few of the activities and events that took place during prostate cancer awareness month, we know there were countless connections made and many heroic acts that took place elsewhere. To each of you who participated and reached out to offer support, we applaud your efforts and encourage you to continue.

Despite a changing population, our mission has not changed: *to communicate timely, personalized and reliable information enabling informed choices regarding detection and treatment of prostate cancer.*

Let's continue to make a difference as we embody our mission.

Hugh McMurray from Platinum Sponsor sanofi-aventis talks with an Us TOO U attendee

Mr. and Mrs. Joe Dickey and a family friend enjoy the Us TOO U graduation dinner

Us TOO Chairman Jim Kiefert welcomes Us TOO University attendees as Tom Kirk, President & CEO, looks on

Chapter leaders attending Us TOO University received a large bag of resources and materials to take home