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**Us TOO**<sup>®</sup>  
PROSTATE CANCER  
EDUCATION & SUPPORT

# HOTSHEET

April 2005

## FDA AGREES TO FILE ABBOTT'S NEW DRUG APPLICATION FOR XINLAY™ TO TREAT METASTATIC HORMONE-REFRACTORY PROSTATE CANCER

Abbott has announced that the U.S. Food and Drug Administration (FDA) has agreed to file the New Drug Application (NDA) for its oral agent Xinlay™ (atrasentan) for the treatment of metastatic hormone-refractory prostate cancer. This action by the FDA indicates the NDA is sufficient to permit a substantive review of the data supporting Xinlay's safety and effectiveness. Abbott expects a response from FDA regarding its application in the fourth quarter of 2005.

Abbott's NDA for Xinlay is based on Phase II and III clinical trials in men with metastatic hormone-refractory prostate cancer. The NDA submission supplies data about the effect of Xinlay on disease progression and delay in time to onset of bone pain." The FDA

(Continued on page 3)

## FINASTERIDE MAY REDUCE MORTALITY BY PREVENTING PROSTATE CANCER

Finasteride may reduce mortality by preventing prostate cancer, according to the results of an analysis of the Prostate Cancer Prevention Trial (PCPT) published in the Feb. 28 Early View issue of *Cancer*. This analysis suggests that the potential detrimental effect of an increased rate of high-grade Gleason tumors would be outweighed by reduced incidence.

"The potential public health impact of the recently completed PCPT is debated," write Joseph M. Unger, MS, from the Fred Hutchinson Cancer Research Center in Seattle, Washington, and colleagues. "The results indicated that the period prevalence of prostate cancer was reduced by 24.8% due to finasteride, whereas an increase in the rate of high-grade tumors (Gleason score 8-10) among men who were diagnosed with cancer also was found (5.0% in the PCPT placebo arm vs. 11.9% in the PCPT finas-

(Continued on page 3)

## PROSTATE CANCER VACCINE HELPS PATIENTS LIVE LONGER

Provenge, a prostate cancer vaccine made by Seattle-based Dendreon Corp., can help patients with severe, advanced disease live a little bit longer, U.S. researchers reported on Wednesday. The therapeutic vaccine added a few months to the lives of men with otherwise untreatable prostate cancer, the researchers said.

One of several experimental tailored approaches to cancer treatment, Provenge is created by mixing a synthetic version of prostatic acid phosphatase (PAP) with dendritic cells harvested from the study patients. This preparation is designed to break the patient's immune tolerance to PAP, an antigen found on most prostate cancer cells

"A therapy that prolongs life yet avoids the side effects of other therapeutic approaches is clearly attractive to patients and physicians alike," said Dr. Eric Small, who led the study at the University of California San Francisco School

(Continued on page 3)

**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](http://www.ustoo.org).

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**2005 US TOO**

**EXECUTIVE COMMITTEE**

Who are the Officers of the Us TOO International Prostate Cancer Education and Support Network Board of Directors? The following is a summary of the appointees who will make up the Board Executive Committee and will be the leaders, working with President/CEO Tom Kirk, to guide Us TOO during the year 2005.

**Jim Kiefert, EdD, Chairman**

Jim was diagnosed with prostate cancer in 1989 at age 50. He had surgery and radiation, which did not eliminate the cancer. Jim retired in 2001 as a school district superintendent having spent 41 years in education serving as a math/science teacher, University professor and public school administrator. Kiefert was a Fulbright Scholar who studied at the American University in Cairo, Egypt and served as Executive Secretary of the Washington Educational Research Association for 19 years.

Kiefert credits his prostate cancer diagnosis with changing his life - sparking changes in diet, exercise, stress reduction, spirituality, and focused on the appreciation of the most important things in life. Jim and his wife Maureen have eight children, 14 grandchildren, and six great grandchildren.

Kiefert and his wife received ACS M2M facilitator training and are now facilitator trainers. They formed and facilitate support groups in The Dalles, OR and Olympia, WA. Jim says, "Living with prostate cancer makes you realize that every day is a gift, to be spent wisely."

**Donald R. Lynam, PhD, Vice Chairman**

Donald Lynam is a prostate cancer survivor, diagnosed in 1997, and active in the Richmond, VA Chapter of Us TOO. He has served as Chairman of the Us TOO Legisla-

participated in the Search Committee for its President/CEO.

In 1999 and 2000, Lynam participated as a consumer reviewer in the U.S. Department of Defense Prostate Cancer Research Program. Lynam has 3 children and 4 grandchildren. He holds an advanced degree in Civil Engineering and in Environmental Health, and recently moved back to Lexington, KY, after retiring in March 2004 from Ethyl Corporation as a corporate vice-president.

**Greg Bielawski, Treasurer**

Greg Bielawski served as Village Manager of Carol Stream, IL, from January 1980 to June 2002 when he retired. He is married with three grown children.

Greg is a prostate cancer survivor diagnosed in 1999 at the age of 54 and is active in many cancer education and advocacy organizations such as the National Cancer Institute's Consumer Advocates in Research and Related Activities (CARRA) network, and the American Cancer Society, of which he is DuPage Illinois Regional Chairman and an Illinois Division Board member.

**Jo Ann Hardy, Secretary**

A native of Detroit, MI, Jo Ann Hardy is the first woman to serve on the Us TOO Board of Directors. This is Hardy's second term as Secretary for the Board, a position that she feels honored to accept.

In September 2000, at the age of 46, Hardy's husband, Jerry, faced a diagnosis of prostate cancer. Hardy and her husband are faithful members of the local Us TOO group at St. Mary Mercy Hospital in Livonia, MI. As Director of Corporate Events for the Episcopal Diocese of Michigan, Hardy is active on the local and national level.

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**XINLAY***(Continued from page 1)*

acceptance of an application is a critical step in our goal of making new therapies that are less toxic available to patients," said John Leonard, M.D., vice president, Global Pharmaceutical Development at Abbott. "For patients whose prostate cancer spreads to other organs, prostate cancer remains incurable. The cancer in hormone-refractory prostate cancer patients often spreads to their bones and patients are left with few treatment options."

Xinlay is an investigational, oral, once-daily, non-hormonal, non-chemotherapy, anti-cancer agent that belongs to a class of compounds known as selective endothelin-A receptor antagonists (SERA™). SERAs antagonize the effect of endothelin-1 (ET-1), one of the proteins thought to be involved in the stimulation of the spread of cancer cells.

Xinlay is currently being studied in several stages of prostate cancer. Trials are ongoing in men with hormone-refractory prostate cancer that has not spread (nonmetastatic), as well as in hormone-naïve men with rising prostate-specific antigen (PSA) following prostate cancer surgery. Additionally, Xinlay is being evaluated in combination trials with approved treatments for advanced prostate cancer.

Abbott continues to explore Xinlay in other cancers, including kidney, ovarian, brain and non-small cell lung cancers. Data from Xinlay clinical trials will be available at scientific sessions this spring.

Abbott's news release and other information are available on the company's Website at [www.abbott.com](http://www.abbott.com). For more information about Xinlay, call (800) 633-9110.

*Abbott Corporate Communications  
11 February 2005*

**FINASTERIDE***(Continued from page 1)*

teride arm). Whether the increased Gleason score was valid or was a histologic artifact is under investigation."

Assuming a 24.8% reduction in prostate cancer incidence for 5 years among U.S. males 55 years or older, the authors estimated that 316,760 person-years would be saved because of finasteride. An absolute increase of 6.9% in the proportion of men with high-grade tumors would reduce the number of person-years saved (PYS) to 262,567. For each absolute increase of 5% in the proportion of patients with high-grade tumors, the number of PYS would be reduced by approximately 39,000.

"The results of the PCPT may have a major impact on population mortality from prostate cancer if they are applied clinically," the authors write. "The potential detrimental effects of an increased rate of patients who have prostate cancer with high-grade Gleason scores would be outweighed by a reduction in incidence."

Limitations of this analysis include assumptions inherent in modeling, size and time requirements preventing use of the predetermined endpoint, use of all-cause mortality rather than cause-specific cancer death as the primary outcome, and assessment limited to 10 years.

"A final, oft forgotten issue is the distinct benefit for the 25% of men who would not be affected by prostate cancer due to finasteride administration," the authors write. "The reduction in cost and morbidity as well as the psychosocial benefits of not having a cancer diagnosis potentially are as great as the life-years saved by this preventive intervention."

*Medscape Medical News  
8 March 2005*

**PROVENGE VACCINE***(Continued from page 1)*

of Medicine.

Researchers presented results at a joint meeting of the American Society of Clinical Oncology, the Prostate Cancer Foundation, the American Society for Therapeutic Radiology and Oncology, and the Society of Urologic Oncology.

Dendreon's vaccine, made with South San Francisco-based Titan Corp., is designed to stimulate the immune system to attack prostate cancer cells generating PAP. A patient's own immune cells are collected, sensitized to the protein, then reinfused into the patient.

Of 127 men with metastatic, hormone-refractory prostate cancer, 82 received the vaccine while 45 received placebo. On average, the men who got the vaccine lived 26 months, compared with 22 months for those on placebo. Three years later, 34% of vaccine patients were still alive, compared with 11% of unvaccinated patients.

Data from this phase III trial is to be used to obtain Food and Drug Administration approval.

*Reuters, 17 February 2005*

**FREE CANCERCARE  
EDUCATION WORKSHOP  
ON ADVANCED  
PROSTATE CANCER**

Another free CancerCare telephone Education Workshop entitled "What's New on the Horizon: Treatment Choices for Men Living with Advanced Prostate Cancer" is scheduled for Wednesday, March 30, 2005 at 1:30-2:30 PM Eastern Time. It features Leonard G. Gomella, MD, Chairman, Department of Urology at Thomas Jefferson University and Floyd Allen, MSW from CancerCare.

Registration is necessary; go to [www.cancercare.org](http://www.cancercare.org) to register online.

## CELECOXIB INHIBITS PROSTATE CANCER GROWTH: EVIDENCE OF A CYCLOOXYGENASE-2-INDEPENDENT MECHANISM

Manish I. Patel MI, Subbaramaiah K, Du B, et al.

**Clinical Cancer Research 11: 1999-2007, 2005**

**Purpose:** Selective cyclooxygenase-2 (COX-2) inhibitors may suppress carcinogenesis by both COX-2-dependent and COX-2-independent mechanisms. The primary purpose of this study was to evaluate whether celecoxib or rofecoxib, two widely used selective COX-2 inhibitors, possess COX-2-independent antitumor activity.

**Experimental Design:** PC3 and LNCaP human prostate cancer cell lines were used to investigate the growth inhibitory effects of selective COX-2 inhibitors in vitro. To complement these studies, we evaluated the effect of celecoxib on the growth of PC3 xenografts.

**Results:** COX-1 but not COX-2 was detected in PC3 and LNCaP cells. Clinically achievable concentrations (2.5-5.0 Mmol/L) of celecoxib inhibited the growth of both cell lines in vitro, whereas rofecoxib had no effect over the same concentration range. Celecoxib inhibited cell growth by inducing a G1 cell cycle block and reducing DNA synthesis. Treatment with celecoxib also led to dose-dependent inhibition of PC3 xenograft growth without causing a reduction in intratumor prostaglandin E2. Inhibition of tumor growth occurred at concentrations (2.37-5.70 Mmol/L) of celecoxib in plasma that were comparable with the concentrations required to inhibit cell growth in vitro. The highest dose of celecoxib led to a 52% reduction in tumor volume and an ~50% decrease in both cell proliferation and microvessel den-

sity. Treatment with celecoxib caused a marked decrease in amounts cyclin D1 both in vitro and in vivo.

**Conclusions:** Two clinically available selective COX-inhibitors possess different COX-2-independent anticancer properties. The anticancer activity of celecoxib may reflect COX-2-independent in addition to COX-2-dependent effects.

### **Researcher's comments:**

"Celecoxib (Celebrex<sup>®</sup>) can mediate anti-tumor effects by mechanisms in addition to targeting COX-2, which is its known target," said lead researcher Dr. Andrew Dannenberg, director of cancer prevention at the Weill Medical College of Cornell University in New York City. "This suggests that the agent's overall anticancer activity may reflect COX-2 inhibition and other properties."

"We were able to demonstrate that at clinically achievable concentrations of the drug in cells that don't express COX-2, the drug still has activity," Dannenberg said. "Based on these results, it's conceivable it will have effects in human tumors that do or do not express COX-2," he added.

However, when the researchers tried the same experiment using rofecoxib (Vioxx<sup>®</sup>), they found the cancer cells continued to reproduce. "This makes the point that all COX-2 inhibitors are not created equal," Dannenberg said.

*Health Day News, 1 March 2005*

## ONCOLOGIC DRUGS ADVISORY COMMITTEE RECOMMENDS AGAINST APPROVAL OF A BROAD INDICATION FOR COMBIDEX

Advanced Magnetix, Inc. and Cytogen Corporation announced today that the U.S. FDA Oncologic Drugs Advisory Committee

(ODAC) voted 15 to 4 to not recommend approval of the proposed indication for Combix, Advanced Magnetix' investigational functional molecular imaging agent.

In making its recommendation, the committee cited insufficient clinical data to support a broad indication for use of Combix to differentiate metastatic from non-metastatic lymph nodes across all cancer types.

A decision by the FDA on Combix is expected by the FDA-designated user fee goal date of March 30, 2005.

"We understand the advisory committee's position relative to a broad label for Combix and look forward to meeting with the FDA to determine appropriate next steps. We remain committed to the ongoing development of Combix," said Jerome Goldstein, Chairman, President and Chief Executive Officer of Advanced Magnetix.

The ODAC is a committee formed by the FDA of external experts to provide the FDA with independent opinions and recommendations in the evaluation of marketed and investigational drugs for use in the treatment of cancer. Voting members practice in the fields of general oncology, pediatric oncology, hematologic oncology, immunology, oncology, biostatistics, other professions and includes consumer and patient representatives.

Combix, an investigational functional molecular imaging agent consisting of iron oxide nanoparticles, is currently being developed for use in conjunction with magnetic resonance imaging (MRI) to aid in the differentiation of cancerous and non-cancerous lymph nodes. Cytogen has exclusive U.S. marketing rights to Combix for all applications and the exclusive right to market and sell for oncology applications in the U.S.

*PRNewswire, 3 March 2005*

## NO EXCESS MORTALITY SEEN FOR MOST U.S. PROSTATE CANCER PATIENTS

In the PSA screening era, mortality rates among most men diagnosed with prostate cancer in the United States are no higher than those in the general population, a new analysis shows. "The bottom line is that most men diagnosed with the disease today can expect to live as long as, or longer than, men their age without the disease," two editorialists comment.

The value of prostate specific antigen (PSA) screening in reducing prostate cancer mortality is still in question, Dr. Hermann Brenner and Dr. Volker Arndt of the German Center for Research on Aging in Heidelberg write in the *Journal of Clinical Oncology* for January 20 (*J Clin Oncol* 23:441-447, 2005). Widespread use of the PSA test in the US since the late 1980s means many more men are living with a diagnosis of prostate cancer, the team points out.

They used "the recently introduced period analysis methodology" to evaluate 5- and 10-year survival rates for 183,484 men diagnosed with prostate cancer between 1990 and 2000 included in the Surveillance, Epidemiology and End Results Program (SEER) database.

Overall, relative 5-year survival rates for prostate cancer patients were 99%, and 10-year survival rates were 95%, Drs. Brenner and Arndt found. "That is, excess mortality compared with the general population was as low as 1% and 5% within 5 and 10 years following diagnosis, respectively," they explain. For the two-thirds of men who had well or moderately differentiated localized or regional prostate cancer, there was no excess mortality at all.

Researchers note that it is possible that earlier diagnosis might not in

itself mean longer survival, but could indicate "mere prolongation of the 'patient career' by advancement in diagnosis." The question of whether PSA screening does in fact reduce mortality from prostate cancer can only be answered by large-scale clinical trials currently underway, they add.

In an accompanying editorial, Dr. George Wilding and Patrick Remington of the Comprehensive Cancer Center at the University of Wisconsin in Madison write: "Given the many uncertainties about this disease, this information alone will be helpful for clinicians and their patients when discussing treatment options and when considering what life will be like living as a prostate cancer survivor."

*Reuters Health, 11 February 2005*

## PROSTATE CANCER VACCINE SHOWS PROMISE

A new vaccine that dramatically slows the recurrence of prostate cancer by marshaling the patient's own immune system to fight tumor cells looks promising in an early trial, researchers report.

This new vaccine uses the patient's own dendritic cells, white blood cells that activate the immune system, to connect antigens to the body's killer cells, called T-cells. The antigen researchers targeted is telomerase, which is secreted by all cancer tumors.

Antigens are protein parts made by viruses or bacteria. Antigens trigger the immune system to attack these invaders. A trick in developing cancer vaccines is training the immune system to recognize tumors as invading antigens.

"This is one of the first steps for the development of a universal cancer vaccine," said lead researcher Dr. Johannes Vieweg, an associate professor of urology and immunology at Duke University. "It may not only be effective in a single tumor system, like prostate cancer,

but against many cancers, because telomerase is overexpressed in a variety of cancers."

In their study, Vieweg's team did tests to be sure the patient's immune T-cells were functioning and also monitored the number and types of T-cells during treatment.

Of the 20 patients in the trial, 19 had an increase in anti-telomerase T-cells (CD8 cells). Among nine patients, dendritic cells were genetically modified to increase the type of T-cells called CD4. All nine patients had an increased immune response, according to the report in the March 15 issue of the *Journal of Immunology*.

Moreover, the researchers found that vaccination was linked to a reduction in tumor cells and also to a slowing of rising PSA levels.

The team found that vaccination allowed the body to distinguish between normal and cancer cells, Vieweg said. "With pinpoint accuracy, we can actually eliminate tumor cells in the patient's body."

The vaccine is designed to be used with patients who have failed usual treatments. Vieweg is quick to say that a cancer vaccine is not a cure, but rather a way to retard the growth of tumors, making cancer something patients can live with.

"This is a very attainable and worthwhile goal, having something that delays disease for a long time without having any side effects," Vieweg said.

"This is a potentially interesting antigen, because cancer cells depend on it for survival," said Dr. Howard Kaufman, vice chairman of surgical oncology at Columbia University, College of Physicians and Surgeons. However, Kaufman believes that the efficacy of the vaccine has not yet been proved. "It's a little disappointing that the clinical response was not better," Kaufman said.

*HealthDayNews, 4 March 2005*

## SATRAPLATIN CHEMOTHERAPY FOR PROSTATE CANCER

Spectrum Pharmaceuticals, Inc. (Nasdaq: SPPI) announced today that data from a 50-patient randomized phase 3 clinical trial on satraplatin as first-line chemotherapy for hormone-refractory prostate cancer (HRPC) has been published in the peer-reviewed journal "Oncology" in an article titled: "Phase III Trial of Satraplatin, an Oral Platinum plus Prednisone versus Prednisone alone in Patients with Hormone Refractory Prostate Cancer: EORTC Genitourinary Tract Group Protocol 30972." The lead author of the publication is Cora N. Sternberg, M.D., FACP, Chief of the Department of Medical Oncology at the San Camillo and Forlanini Hospitals in Rome, Italy, who is also a principal investigator in the ongoing Phase 3 pivotal trial (the SPARC trial).

Previously reported summary data from the study demonstrated the following in the satraplatin arm: (i) a statistically significant doubling in progression-free survival; and (ii) a numerical, although not statistically significant, improvement in median overall survival.

"We are pleased to see the publication of these data on satraplatin in a peer-reviewed journal, especially since this dataset formed the basis of the ongoing phase 3 pivotal trial evaluating satraplatin as second-line chemotherapy for hormone-refractory prostate cancer," stated Rajesh C. Shrotriya, Chairman, Chief Executive Officer and President of Spectrum Pharmaceuticals.

Enrollment for the phase 3 pivotal SPARC trial evaluating satraplatin as second line chemotherapy in HRPC is proceeding as planned. Submission of a New Drug Application (NDA) filing is expected to be completed, assuming positive data, in the second half of 2006.

Data from this study demonstrated that satraplatin treatment led to a statistically significant ( $p=0.023$ ) doubling of progression-free survival, with the median time to disease progression or death of 5.2 months for satraplatin versus 2.5 months for the control arm.

Satraplatin was relatively well tolerated in this study, with no Grade 3-4 toxicities observed for hemoglobin, nausea, fever or pulmonary toxicity.

*PRNewswire, 28 February 2005*

## CAROTENOIDS MAY PROTECT AGAINST PROSTATE CANCER

Dietary lycopene and other carotenoids may be protective against prostate cancer, Australian and Chinese researchers report in the March 1st issue of the International Journal of Cancer (*Int J Cancer* 113:1010-14, 2005). The findings confirm those of other studies.

Researchers conducted a case-control study in southeast China. Involved were 130 patients with histologically confirmed adenocarcinoma of the prostate, and 274 controls. After adjustment for factors including, age, total fat and caloric intake as well as a family history of prostate cancer, diet appeared to have an influence.

The risk of prostate cancer declined with increasing consumption of lycopene, alpha-carotene, beta-carotene and other carotenoids. Consumption of foods including tomatoes, spinach and citrus fruits was also inversely associated with cancer risk.

Compared to those with the lowest intake of lycopene, those with the highest had an odds ratio for prostate cancer of 0.18. Researchers conclude that "carotenoids in vegetables and fruits may be inversely related to prostate carcinogenesis among Chinese men."

*Reuters Health, 24 February 2005*

## HIGH LEVELS OF VITAMIN E CUT PROSTATE CANCER RISK

High blood levels of the major vitamin E components, alpha- and gamma-tocopherol, seem to cut the risk of prostate cancer by about 50 percent each, a study shows.

The findings are based on an analysis of 100 individuals with prostate cancer and 200 "controls" participating in the Alpha-Tocopherol, Beta-Carotene Cancer Prevention (ATBC) Study, involving nearly 30,000 Finnish men.

Men with the highest baseline levels of alpha-tocopherol in their blood were 51% less likely to develop prostate cancer than those with the lowest levels, report investigators in the March 2, 2005 issue of the Journal of the National Cancer Institute (NCI).

Similarly, men with the highest levels of gamma-tocopherol were 43% less likely to develop the disease compared with men with the lowest levels. Further analysis showed that the link between high tocopherol levels and low cancer risk was stronger among subjects using alpha-tocopherol supplements than among non-users.

This supports the original findings from the ATBC study, which showed that daily vitamin E supplementation reduced the risk of prostate cancer by 32 percent.

Dr. Demetrius Albanes, from the NCI in Bethesda, Maryland, and colleagues believe that the antioxidant activity of vitamin E may be particularly important to the associations they observed in the current study because oxidative stress has been tied to the development of prostate cancer.

However, alpha-tocopherol can also enhance the immune response, which may also play a role in the benefits seen, they add.

*Reuters Health, 2 March 2005*

## COOPERATIVE GROUP CLINICAL TRIAL FOR PROSTATE CANCER PATIENTS WITH FATIGUE AND ANEMIA: E1Z01

Fatigue can be a major problem for patients with prostate cancer and is often related to anemia. The Eastern Cooperative Oncology Group is conducting a randomized study (study number: E1Z01) to find a more effective therapy for advanced prostate cancer patients who have fatigue and anemia.

Treatment A is Epoetin alfa (erythropoietin), an injected medication that can stimulate the bone marrow to produce red blood cells, improving anemia. Treatment B is a combination of Epoetin alfa and a low dose of oral dexamethasone. Dexamethasone, a corticosteroid, has been shown in laboratory studies to improve the effectiveness of erythropoietin. In addition, corticosteroids, can improve quality of life, reduce pain, and decrease fatigue in cancer patients.

The study will last for 12 weeks, and will require monthly visits for blood tests and interviews about fatigue, symptoms, and quality of life. By conducting this study, the research team hopes to find treatments to better control cancer-related fatigue, anemia, and other symptoms associated with advanced prostate cancer.

If you are interested in finding out more about this trial and if you are eligible to participate, discuss this study with your physician. You can also find out more details through the Us TOO website ([www.ustoo.org](http://www.ustoo.org)) in the Clinical Trials section.

You may also contact the Study Chair, Dr. Victor Chang via e-mail ([victor.chang@med.va.gov](mailto:victor.chang@med.va.gov)), or contact the research nurse, Ms. Jan Einhorn, RN via e-mail ([jan.einhorn@med.va.gov](mailto:jan.einhorn@med.va.gov)) or by call her at (973) 395-7095.

## \$13.4 MILLION FROM NIH GOING TO STUDIES OF CANCER BIOMARKERS

Biomarker cancer research is getting additional funding from the National Institutes of Health (NIH; Bethesda, Maryland) and its National Cancer Institute (NCI).

Two research teams from 10 cancer research institutions will receive two-year awards totaling \$13.4 million. According to NIH, the grants reflect a new collaborative team approach to develop the standard tools and resources needed to accelerate protein biomarker discovery to provide new and highly specific approaches to the early detection and diagnosis of cancer.

Researchers will use transgenic mouse models of human cancers to

study current proteomic technologies, compare results, and provide reference data sets and biological resources for widespread research use throughout the cancer research community. Scientists at NCI hope this approach will enable comparability of results among multiple laboratories currently using different proteomic technologies, in addition to providing direction for targeting biomarkers that signal the earliest stages of cancer in humans.

Researchers expect that the common data sets and resources will make it easier to develop and test the next generation of technologies for biomarker discovery. Once developed, data and information will be distributed through the cancer Biomedical Informatics Grid, an open-source, open-access, information network for researchers.

*Medical Device Daily*

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- ◆ **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

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

**FDA APPROVES NEW DEVICE FOR DIAGNOSING AND TREATING PROSTATE CANCER**

The U.S. Food and Drug Administration recently approved a new medical device for prostate biopsies and improving the accuracy of less-invasive cancer treatments. Created by St. Louis-based Envisioneering Medical Technologies, TargetScan® is the latest innovation in prostate mapping, biopsy and cancer treatment guidance. Combining 3-D image acquisition with a stationary probe, this new technology helps physicians plan and execute targeted prostate biopsies – potentially improving patients' cancer treatment outcomes with less-invasive procedures. Current procedures require urologists to hold and pivot a probe with one hand, while performing a needle biopsy with the other. Inherent variables in performing this technique can miss as much as 20-30% of potential cancers, according to Dr. Gerald Andriole, professor of surgery and chief of urology at Washington University School of Medicine and director of the Urological Research Center at Barnes-Jewish Hospital in St. Louis.

"We've learned that current diagnostic tools are inadequate – missing cancer in some patients while over testing others," said Andriole, who after examining TargetScan joined Envisioneering's medical advisory board. "With TargetScan, we anticipate improved cancer detection – saving time, money and possibly lives."

TargetScan also impacts cancer treatment, according to Dr. Jeff Michalski, Department of Radiation Oncology at Washington University School of Medicine. "The clinical benefit from the TargetScan 3-D probe is obvious," says Michalski. "By eliminating the need to physically move the probe, the prostate position will be stabilized allowing for improved radioactive seed implantation and better brachytherapy clinical outcomes."

TargetScan is available in select urology clinics across the country for field testing. Envisioneering is planning a widespread TargetScan launch along with the American Urology Association conference in San Antonio this May.

For more information, please visit [www.envisioneeringmedical.com](http://www.envisioneeringmedical.com).

*PRNewswire, 24 February 2005*

**AN-152 ENTERS CLINICAL DEVELOPMENT**

Aeterna Zentaris, Inc. has begun their phase I dose-ranging study for the targeted anti-cancer agent AN-152. This is a novel cytotoxic conjugate that has the potential to selectively and specifically target cancer cells that express luteinizing hormone-releasing hormone receptors (LHRH).

The study will evaluate the safety (including maximum tolerated dose and dose-limiting toxicity) and pharmacokinetics of intravenously-administered AN-152 in patients with LHRH receptor positive ovarian, endometrial or breast cancer.

AN-152 is a cytotoxic conjugate designed to achieve differential delivery or targeting of doxorubicin to cancer versus normal cells. Within AN-152 is that chemically links to an LHRH agonist, a modified natural hormone with affinity for the LHRH receptor.

The clinical development of AN-152 may offer a safer and more effective profile, while selectively and specifically targeting cancer cells expressing LHRH.

*CancerConsultants.com  
23 February 2005*

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