Us TOO® PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

February 2006

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GENOME PROJECT TARGETS CANCER

NIH earmarks $100 million for study of malignant tumors at molecular level

In a bold but uncertain bid to spur cancer treatment, federal medical researchers announced Tuesday a $100 million project to begin cataloging the disease's molecular underpinnings. The Cancer Genome Atlas, as the project is called, will start as a three-year pilot identifying the genes behind two or three types of cancerous tumors. If the research proves promising and affordable, it would be expanded to study thousands of cancerous tumors.

Describing the effort as potentially "revolutionary," officials at the National Institutes of Health asserted that the resulting knowledge could quickly lead to the development of more effective cancer drugs and therapies. "This is really the beginning of an era," said Dr. Elias A. Zerhouni, director of the NIH, the government's main medical research arm and a distributor of funding. "What I think we will see is an acceleration of discovery."

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THE UNSEEN PATIENT: COMPANIONS AND FAMILY MEMBERS NEED AND RECEIVE CARE, TOO

Toll-free teleconference on 2/16/06 kicks off release of the Circles of Love Discussion Guide

Us TOO recognizes that prostate cancer is a disease of the patient, the partner or spouse, and the family. While the patient experiences cancer in their body, those closest to the patient have an experience of prostate cancer that is also very real. Companions and family members need help too.

In the 2005 Us TOO book, the Circles of Love Collection, we met sixteen families and couples facing prostate cancer. While acknowledging the challenges of the patient, these real-life inspiring stories focused on the invisible patients: the companions, spouse and family members of men with prostate cancer. Their stories provide readers countless opportunities for reflection and discussion. While the complete Circles of Love Care Kits were provided to each chapter last summer, additional care kits (and the components) are available to chapters at a significantly reduced price.

In mid-February 2006, Us TOO will release the Circles of Love Collection Discussion Guide. This tool is designed for use with the Circles of Love Collection book and Care Kit to further bring those remarkable stories to life. Whether you use the discussion guide as part of an Us TOO chapter meeting or while sitting at the kitchen table, each section provides compelling questions to consider and discuss, along with fall '05 updates from many of those featured in the Circles of Love Collection. In addition, the discussion guide features absolutely everything needed to host a companions and families event in your area.

A North-American interactive conference call will kick-off the release of the Discussion Guide. This call will feature Shirley Grey and Mo Keifert, Us TOO chapter participants and leaders of companions and families support groups. The call will also feature Jo Ann Hardy,

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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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THE UNSEEN PATIENT

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Us TOO Board of Directors. These three women are all spouses of prostate cancer patients and members of the Us TOO Advisory Panel for companion & family care. Rounding out the Advisory Panel is Elizabeth Cabalka, nationally known author and speaker in the area of Caregiver Advocacy as well as Us TOO's Karen Bacher. Most importantly, you will be able to participate in the call by sharing ideas and asking questions about supporting those who create a circle of love around prostate cancer patients.

This FREE 60-minute toll-free dial-in call will take place on Thursday, February 16, 2006 at 9:00 pm ET / 8:00 pm CT / 7:00 pm MT / 6:00 pm PT. Simply dial (800) 967-7135 five to ten minutes before the call.

For additional information about The Circles of Love Initiative or the kick-off conference call, please contact Elizabeth at 320-980-0437 or elizabeth@ustoo.org. The Circles of Love Care Kit and all its individual components are available for purchase at by calling the Us TOO offices at 800-808-7866 or by accessing <www.ustoo.org>.

BIG GRANT TO PREDICT PROSTATE CANCER OUTCOMES

The federal government has awarded UC Irvine $9.5 million to develop a way to forecast the outcome of a person's prostate cancer at the time they're diagnosed, campus officials said today. The grant is among the 10 largest in the university's history and will be overseen by pathologist Dan Mercola, who will lead a team of scientists from UCI's School of Medicine.

"The goal of the new study is to develop a 'gene signature' of prostate cancer for newly diagnosed patients based on a tumor biopsy or blood examination," UCI says in a news release. "This signature will let patients know if they have an aggressive form of cancer — allowing them to better understand their disease and make crucial decisions for appropriate early-stage treatment."

Mercola said in the release, "We are aiming to meet a critical unmet need in prostate cancer treatment. Up to 30 percent of men with prostate cancer do not need radical treatments like radiation or surgery, and this test will allow us to determine who these people are."

Orange County Register
14 December 2005

STUDY SHOWS PROCYON'S PSP94 DIAGNOSTIC MARKER IS BETTER

Toronto study to be published in prestigious Journal of Urology

Procyon Biopharma Inc. (TSX:PBP), a biotechnology company developing innovative therapeutics in the fields of cancer and HIV/AIDS, announced today that the findings of an extensive study, conducted by Dr. Robert K. Nam, MD, FRCSC, Assistant Professor of Surgery, Division of Urology at the Sunnybrook and Women's College Health Sciences Centre, University of Toronto, with its Prostate Secretory Protein of 94 amino acids (PSP94) immunoassays for the diagnosis and prognosis of prostate cancer, will be published in the Journal of Urology. The study conducted with 1212 patients who underwent biopsy confirmation of prostate cancer due to either an abnormal digital rectal examination (DRE) or high Prostate Specific Antigen (PSA) showed that PSP94 serum levels were a better predictor of the aggressivity of the cancer than PSA or FTPSA (Free to Total PSA ratio).

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GENOME PROJECT

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Often referred to as a single disease, cancer is actually a collection of more than 200. They develop, scientists believe, after genetic changes cause cells to mutate and grow wildly.

The cancer project, NIH officials said, would find the common features underlying the genetic malfunctions – most likely not a single glitch causing various cancerous cells to flourish, but perhaps a set of glitches that each leads to a number of diseases.

"It will be an important step in our understanding of the genetic components of cancer and the genetic susceptibilities of people affected by cancer," said Dr. Andrew C. von Eschenbach, director of the National Cancer Institute and acting head of the Food and Drug Administration. In 2003, scientists finished mapping the human genome, the genetic code that guides a body's functions and characteristics.

Sequencing cancer genes is a natural follow-up because researchers can use the blueprint of normal human DNA to identify cancer genes. They can also capitalize on the mapping technologies already developed.

Supporters of the cancer project argue that the vast diversity of cancer genes requires NIH involvement. They say that more effective treatments can't be developed without the better understanding that sequencing cancer genes would provide. "The more we learn about cancer at the molecular level, the more chance we have of being successful in treating cancer," said Dr. Bob Strausberg, vice president for human genomic medicine at the J. Craig Venter Institute in Rockville, founded by the scientist who raced against the government to be the first to log the human genetic code.

Challenges

But the sequencing of cancer genes also presents its own challenges. The work is costly. Because cancer causes the cells to mutate, each tumor cell has its own genome, so mapping every tumor would be equivalent to undertaking scores of human genome projects – as many as 12,500, by one estimate. "There are many technical problems we have encountered, and acquiring the right sample collections is always problematic," said Dr. Michael Stratton of the Wellcome Trust Sanger Institute in Britain, which studies cancer genes.

Researchers must also review many genes before distinguishing those that play important roles in causing mutations. "Sorting the 'passengers' from the 'drivers' is a significant issue," Stratton said.

Another obstacle is that no two cells in a malignant tumor might be identical. As a result, successful sequencing of some cancer genes might miss others. If a missed gene plays a key role in causing malignancy, treatment would suffer.

For that reason, Dr. Garth R. Anderson, a cancer geneticist at the Roswell Park Cancer Institute in Buffalo, N.Y., criticized the project for taking money from what he said was more worthwhile research promising early diagnosis of tumors and more lasting treatments.

"Focus your efforts on that direction, not on finding 'miracle' targets and then 'miracle' drugs," Anderson said. NIH, he said, is "putting a lot of effort into something that I don't think will accomplish much therapeutically."

There has been some progress, however. A number of private institutions have been mapping various cancer genes. And the research has led to the development of several drugs, such as Novartis Pharmaceuticals Corp.'s Gleevec®, which has proven successful in treating a form of leukemia.

During research into colon cancer gene mutations, Dr. Victor Velculescu, an assistant professor of oncology at Johns Hopkins, has uncovered some common features with breast, gastric and brain cancers. Velculescu described identifying cancer genes as a crucial but doable first step in learning about the mechanisms driving cancer. "The much harder part will be understanding what the genes do and designing drugs," he said.

Outlining the pilot project, Dr. Francis S. Collins, director of the National Human Genome Research Institute, said the intent is to fund potentially promising research into two or three types of tumors, such as colon cancer and leukemia. The Genome Atlas project will also support collection of cancer tissue samples and further development of mapping technologies.

"The hope, as this project goes forward, is that we'll have better and better technologies so the efficiency will increase as well as the costs will go down," said Anna D. Barker, deputy director of the National Cancer Institute.

Other research

The $100 million will come from existing funds, though NIH officials emphasized that they would continue to support other kinds of research. The agency has not yet solicited bids from research groups for the work.

While acknowledging the complexity of the undertaking, officials expressed optimism that the pilot project would show enough positive results to warrant its expansion into a full-fledged effort. They will monitor the progress of this pilot project's work as it moves forward.

The hope is that the findings would lead to the development of "targeted" therapies to attack each cancer patient's particular condition. "These targeted drugs have the potential of being more effective than the current chemotherapy regimens," said Dr. Bruce E. Johnson of the Dana Farber Cancer Institute in Boston.

Baltimore Sun, 13 December 2005

DR. RUTH WESTHEIMER

PROCYON'S PSP94

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While about 30% of males over the age of 50 are believed to have prostate cancer as determined by pathology staining of prostate biopsy samples, the overall mortality from the cancer is low due to the fact that most of the time prostate cancer is slow growing. However it is critical to detect those cases where the cancer is aggressive and could be fatal. "This is the first report of a serological marker which can predict both the presence of prostate cancer and help identify patients with high grade or stage disease at diagnosis better than PSA or FTPSA ratio in a clinical setting", said Dr. Nam.

In the study, of the 1212 patients who underwent the diagnosis, 596 were found to have cancer. Among a subgroup of 649 men where PSA had a low predictive value and DRE was normal, 260 were found to have cancer. In this subgroup, PSP94 levels were able to discriminate between patients with high grade disease (Gleason score

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SPECIAL EVENTS FEATURING RENOWNED SEX THERAPIST DR. RUTH WESTHEIMER

When a man first comes to his physician for treatment of erectile dysfunction (ED), the first option usually offered is medication. However, prescription drugs aren't the answer for everyone. In fact, studies show that ED drugs don't work for approximately 30 percent[1] of patients; and they're not appropriate for men who have ED as a result of prostate surgery.

The good news is that there are other options, including advanced, drug-free solutions like penile implants. Us TOO members can discover more information about ED solutions through a series of special events featuring renowned sex therapist Dr. Ruth Westheimer. Dr. Ruth's "Evening for Two" will take place in four cities: Phoenix (February 14), Nashville (March 28), Houston (April 25) and Cleveland (May 17).

Dr. Ruth has been giving sex and relationship advice for over 20 years. In her most recent book, Dr. Ruth's Sex After 50: Revving Up Your Romance, Passion and Excitement, she stresses the importance of maintaining sexual intimacy at any age. The good news is, ED doesn't have to spell the end of a satisfying sex life.

Each of Dr. Ruth's "Evening for Two" events include prominent local urologists, who will present information about ED solutions and answer any medical questions you may have. Hors d'oeuvres and cocktails will be served, and advance registration is required. Tickets are $25 per couple, with all proceeds benefiting Us TOO International Prostate Cancer Education and Support Network.

To find out if this event is right for you and your partner, take the Sexual Health Inventory for Men questionnaire online at by calling 877-4ED-CURE or by accessing <www.EDcure.org>.

1. Goldstein I. Lue TF. et al. N Engl J Med 1998; 338:1397-1404

VITAMIN D DEFICIENCY CAN INCREASE CANCER RISK

Correcting vitamin D deficiency could significantly lower the risk of several types of cancer, investigators report. "The cost of a daily dose of vitamin D3 (1000 IU) is less than 5 cents, which could be balanced against the high human and economic costs of treating cancer attributable to insufficiency of vitamin D," they point out.

Vitamin D can reduce the risk of many types of cancer by block the growth of new blood vessels that allow cancer to thrive, a process known as angiogenesis. It can also stimulate cell adherence and "enhance intercellular communication through gap junctions, thereby strengthening the inhibition of cancer cell growth that results from tight physical contact with adjacent cells within a tissue," Dr. Cedric F. Garland and colleagues note in their article, published in the February 2006 issue of the American Journal of Public Health.

Garland, from the University of California, San Diego in La Jolla, and his colleagues performed a search of published studies, identifying 63 observational studies on vitamin D and its association with cancers of the colon, breast, prostate and ovary. Twenty of 30 studies of colon cancer or precancerous colon polyps found a statistically significant benefit of vitamin D. Similar results were observed for 9 of 13 studies concerning breast cancer risk, 13 of 16 with prostate cancer risk, and 5 of 7 with ovarian cancer.

The authors recommend 800 to 1000 IU vitamin D supplementation per day, and believe that these dosages would not produce toxicity.

Reuters Health, 9 January 2006

COUNSELING HELPS SEX LIFE AFTER PROSTATE CANCER

Even a few counseling sessions on sex after prostate cancer can help improve a couple's sex life, at least in the short term, research hints. Researchers found that among 84 prostate cancer survivors, those who completed four therapy sessions -- whether they attended alone or with their partners -- reported better sexual functioning 3 months later. Similarly, their wives and partners said their sex lives were more satisfying.

These improvements, however, began to wane 6 months after therapy. The bottom line, according to the study authors, is that while counseling can help couples rekindle their sexual relationship after prostate cancer, a lingering question is how to make the benefits last.

Dr. Andrea L. Canada and her colleagues at the University of Texas M.D. Anderson Cancer Center in Houston report the findings in the December 15, 2005 issue of the journal *Cancer*.

Sexual dysfunction is a common side effect of surgery and radiation treatment for prostate cancer. Studies have consistently found that the large majority of men have erectile dysfunction (ED) after treatment, while many may also have a low libido and trouble reaching orgasm.

Medications, like Viagra, can help some patients, but ED caused by prostate cancer treatment does not respond as well to drugs as other forms of ED do, Canada and her colleagues note.

To see whether counseling sessions could help couples improve their sex life, the researchers randomly assigned 84 men and their partners to one of two groups. In one group, men attended counseling alone, while couples in the second group went to sessions together.

Counseling focused on open communication between partners, treatment options for ED and how to enjoy sex despite ED. Both groups received four sessions plus "homework" assignments.

Immediately following treatment and 3 months later, both men and their partners reported improvements in their sex life, regardless of which group they were in. In addition, more men began using ED treatments - more than 50 percent after counseling, versus 31 percent before.

However, the improvements both partners reported in their sex life had begun to wane by the 6-month mark, the study found. Women, in particular, seemed happiest immediately after the counseling sessions ended.

It's possible, the researchers speculate, that over time, couples went back to their "perfunctory" sexual routine, especially as more men received treatment for their erectile problems. But the success of counseling, according to Canada and her colleagues depends on men being able to shed their beliefs about the all-importance of the erection and the ability of a "magic pill" to restore their sex life.

"It is not surprising that men and women prefer the magic pill," the researchers write, "but if we can create more realistic expectations, perhaps they will be willing to try interventions that focus less on penile rigidity and more on relationship flexibility."

Reuters Health, 15 December 2005

PROCYON'S PSP94

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>8), from moderate grade and low grade disease, statistically, while PSA and FTPSA could not. Patients with low serum PSP94 levels had a high probability for having prostate cancer detected at biopsy.

"We are very pleased with the findings of this extensive study which shows that our diagnostic test for serum PSP94 would be an excellent serological marker to be used in combination with PSA for seeking out patients with aggressive prostate cancer which can be fatal," said Hans J. Mäder, president and chief executive officer of Procyon Biopharma. "The publication of the results in a peer-reviewed journal complements the marketing efforts of our partner, Medicorp, who is currently marketing for research purposes the three PSP94 assays developed by Procyon," he concluded.

About PSP94

PSP94 is one of the three major proteins secreted in the seminal fluid, together with PSA and Prostatic Acid Phosphatase (PAP). PSP94-based test kits measure the amount of free PSP94, bound PSP94 and PSP94 binding protein present in the blood, the relative ratios of which are believed to have utility in prostate cancer prognosis, diagnosis and monitoring. These test kits differentiate between patients with prostate cancer and patients with benign conditions among patients who underwent a biopsy for prostate cancer.

The PSP94-based test kits have the potential to significantly reduce the number of first and repeat prostate biopsies thus reducing the associated cost, morbidity and infection risk. Recent studies also indicate that the PSP94-based test kits were able to predict patients suffering from a more aggressive disease. PSP94 was found to be a strong predictor of relapse post-radiotherapy as well as following radical prostatectomy.

Procyon Biopharma, Inc.
2 December 2005

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INTERLEUKIN-17 RECEPTOR-LIKE GENE IS A NOVEL ANTIAPOPTOTIC GENE HIGHLY EXPRESSED IN ANDROGEN-INDEPENDENT PROSTATE CANCER

You Z, Shi X-B, DuRaine G, et al

Cancer Res 66:175-83, 2006

We have recently identified a new gene, interleukin-17 receptor-like (IL-17RL), which is expressed in normal prostate and prostate cancer. This investigation is focused on the role of IL-17RL in prostate cancer. We found that IL-17RL was expressed at significantly higher levels in several androgen-independent prostate cancer cell lines (PC3, DU145, cds1, cds2, and cds3) and tumors compared with the androgen-dependent cell lines (LNCaP and MLC-SV40) and tumors. In an in vivo model of human prostate tumor growth in nude mice (CWR22 xenograft model), IL-17RL expression in tumors was induced by androgen deprivation. The relapsed androgen-independent tumors expressed higher levels of IL-17RL compared with the androgen-dependent tumors. Overexpression of IL-17RL in tumor necrosis factor (TNFα)–sensitive LNCaP cells inhibited TNFα-induced apoptosis by blocking activation of caspase-3 downstream to caspase-2 and caspase-8. Reciprocally, knocking down IL-17RL expression by small interfering RNA induced apoptosis in all the prostate cancer cell lines studied. Taken together, these results show that IL-17RL is a novel antiapoptotic gene, which may confer partially the property of androgen-independent growth of prostate cancer by promoting cell survival. Thus, IL-17RL is a potential therapeutic target in the treatment of prostate cancer.

COUGAR BIOTECHNOLOGY BEGINS PHASE I/II TRIAL FOR CB7630

Cougar Biotechnology has announced that the first patient has been enrolled in the Phase I/II trial of the company's drug CB7630 (abiraterone acetate), an orally active inhibitor of the steroidal enzyme 17alpha-hydroxylase/C17, for the treatment of advanced prostate cancer.

The trial is an open label, dose-escalating study to evaluate the safety and efficacy of CB7630 administered daily to patients with chemotherapy-naive hormone refractory prostate cancer with a rising PSA prostate specific antigen despite hormonal therapy.

FDA News, 14 December 2005

2006 US TOO INTERNATIONAL BOARD OF DIRECTORS APPROVED

At the last Board of Directors meeting, held in December 2005, the 2006 slate of Board officers and members was approved. There were no changes from the 2005 Board, except that Bob Hustead, MD, completed his term of service. All thanked him for his 4 years of contributions to the development and growth of the organization. Officers are Jim Kiefert, EdD, Chairman, Don Lynam, PhD, PE, CIH, Vice-Chairman, Jo Ann Hardy, Secretary, and Greg Bielawski, Treasurer. Board members are Chris Bennett, Bob Fidoten, PhD, Carl Frankel, Russ Gould, Tom Hiatt, Bill Palos, Harry Pinchot, Joe Piper, and Jim Raby.

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