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PROSTATE CANCER
EDUCATION & SUPPORT

HOTSHEET

March 2008

SUPREME COURT DECLINES EXPERIMENTAL DRUGS CASE

The Supreme Court refused Monday to review a ruling that terminally ill patients have no constitutional right to be treated with experimental drugs — even if that means the patient will likely die before the medicine is approved.

A federal appeals court, siding with the Food and Drug Administration, last year said the government may deny access to drugs that have not gone through extensive testing and received FDA approval. The process can take years. The Supreme Court did not explain its decision to leave the appeals court ruling undisturbed. Chief Justice John Roberts did not take part in the action.

The Abigail Alliance for Better Access to Developmental Drugs and the Washington Legal Foundation sued the FDA in 2003, seeking access for terminally ill patients to drugs that have undergone preliminary safety testing in as few as 20 people but have yet to be approved. Abigail Alliance was created by Frank Burroughs, whose daughter, Abigail, was denied access to experimental cancer drugs and died in 2001. The drug she was seeking was approved years later.

The alliance said all it was asking for "is a right for terminally ill patients

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EDITORIAL: PROVENGE PRESSURE BUILDS ON FDA

In the coming weeks, it looks increasingly likely that the US Congress will launch an investigation into the circumstances behind the FDA's decision last May to delay approval of Provenge®, a recombinant therapeutic vaccine developed by Dendreon for use in terminally ill patients with androgen-independent prostate cancer. Cancer patients have been exasperated by the agency's decision to ignore an advisory committee recommendation made in March, which gave the green light for full approval. The flip-flop came following the panel meeting, after FDA received three letters sharply critical of Provenge's safety and efficacy, which were subsequently leaked to the press. With allegations of 'dirty tricks' by agency officials and undisclosed, potentially damaging corporate ties associated with at least one of the letter writers, the onus is now on the FDA to affirm the legitimacy and impartiality of its regulatory process.

Why did FDA ask Dendreon for additional clinical, chemistry and manufacturing data for Provenge against scientific advice? Certainly, patient groups, denied a 'lifesaving' therapy, would like to know why. And in a field where Provenge represents not only a pioneering technical approach but also the first

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INTERIM ANALYSIS SUPPORTS CONTINUATION OF CELL GENESYS' VITAL-1 PHASE 3 CLINICAL TRIAL OF GVAX IMMUNOTHERAPY FOR PROSTATE CANCER

Cell Genesys, Inc. announced that the Independent Data Monitoring Committee (IDMC) for VITAL-1, the first of two ongoing Phase 3 clinical trials of GVAX immunotherapy for prostate cancer, has completed a pre-planned interim analysis and has recommended that the study continue. This event-driven interim analysis was designed to determine whether the study should continue to completion and took place in the time frame originally estimated. As is customary to preserve study blinding, the IDMC provided no information to the company other than the recommendation to continue the trial.

"The IDMC's recommendation to continue with the VITAL-1 trial represents an important step forward in the Phase 3 development of GVAX immunotherapy for prostate cancer and in our effort to make this product available as a new treatment option for men with prostate cancer," stated Robert Dow, MBChB, chief medical officer of Cell Genesys. "Moreover,

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SUPREME COURT SIDES WITH WASHINGTON UNIVERSITY IN OWNERSHIP OF TISSUE CASE

The U.S. Supreme Court on Tuesday upheld lower court rulings and sided with Washington University in St. Louis, MO in a decision that allows the university to keep tissue and blood samples donated to the school for prostate cancer research. In 2003, Washington University filed suit against Dr. William Catalona, a former employee, to ask the courts to determine who should control the donated samples stored in Washington U.'s biorepository. Catalona and some research participants said tissue donors had a right to require that the samples be forwarded to Catalona at Northwestern University, where he had assumed a faculty position after resigning from Washington University.

In June 2007, the 8th US Circuit Court of Appeals upheld a lower court ruling that tissue and blood samples donated to Washington University for prostate cancer research belong to the institution. The Court said at the time the donors voluntarily made a gift for prostate cancer research to Washington U. when they donated their biological samples and, therefore, the specimens belong to the school.

"Washington University takes its obligation to research participants very seriously," Dr. Larry Shapiro, executive vice chancellor for medical affairs and dean of the Washington University School of Medicine, said in a statement. "We will continue to use the tissues and serum samples for the purpose they were originally intended, which is prostate cancer research. It is our hope that use of the repository will lead to important advances. As we have said throughout the case, we encourage scientists both within the university community and those affiliated with other institutions to request access to the repository for their own prostate cancer studies."

Editors' Note: *Us TOO is disappointed by this news as Us TOO filed an Amicus brief to the US Supreme Court in November supporting Dr. Catalona's position. Readers may also recall that Us TOO also filed a similar brief at the appellate level as well believing that patients have a right to decide the use of their tissue and serum samples.*

NO LINK BETWEEN ANDROGEN LEVELS AND RISK FOR PROSTATE CANCER

Blood levels of androgens and other sex hormones do not appear to be related to the risk for prostate cancer. The finding comes from a huge pooled analysis of data from 18 studies, published online January 29 in the Journal of the National Cancer Institute (*J Natl Cancer Inst*, Vol. 100, pp. 158-9, 2008). It "confirms the lack of evidence to support an androgen-prostate cancer hypothesis," according to an accompanying editorial.

A link between elevated androgen levels and an increase in the risk for prostate cancer has been widely hypothesized, despite little supportive epidemiologic evidence, commented Paul Godley, MD, PhD, and colleagues from the University of North Carolina, Chapel Hill, in an accompanying editorial.

The new analysis provides no evidence of such a link, however. An international collaboration of researchers, headed by Andrew Roddam, DPhil, from the University of Oxford, UK, took another look at the original data collected in the 18 studies, consisting of 3,886 men with prostate cancer and 6,438 controls. Each of the studies had looked at the relation between androgens and the risk for prostate cancer, but the results were inconclusive; some suggested a positive association, but many of the studies had limited power, the researchers comment. In the new analysis, all of the data from these previous studies were pooled together. The team looked at blood samples taken before the men developed prostate cancer and analyzed serum concentrations of testosterone, free testosterone, dihydrotestosterone, dehydroepiandrosterone sulfate, androstenedione, androstanediol glucuronide, estradiol, and calculated free estradiol. They found no significant relation between the serum levels of any of these hormones and the risk of developing prostate cancer.

This is an "impressive pooled analysis" that enhances "our understanding of prostate cancer epidemiology," the editorialists comment. It also offers a new opportunity, because it now

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EDITORIAL: PROVENGE PRESSURE BUILDS ON FDA *(Continued from page 1)*

nontoxic treatment for prostate cancer, investors and the oncology community would like to know why.

Over recent months, pressure has been mounting for an answer. Thousands of letters have purportedly been written to FDA, members of Congress and the Department of Justice. Demonstrations have been held outside FDA's offices. And the prostate cancer patient advocacy group, CareToLive, has filed lawsuits against FDA contesting the decision and demanding access to Provenge. It has even run an ad campaign on buses in the Washington, DC, area critical of the FDA's handling of Provenge.

The signs are that all this is beginning to register on the political radar. In December, three Congressmen—Mike Michaud (D-ME), Dan Burton (R-IN.) and Tim Ryan (D-OH) —wrote to the House Energy and Commerce Committee citing “ethical violations” and the need for “full disclosure...to restore confidence in the FDA.” An inquiry is now expected.

Part of the reason for all the hoopla is that, apart from FDA's decision to ignore scientific advice, there were also several irregularities in the process.

At least one of the Office of Cellular, Tissue and Gene Therapies Advisory Committee members who voted against Provenge and then wrote to FDA to criticize the approval recommendation —Howard Scher of Memorial Sloan-Kettering Cancer Center—failed to disclose important competing financial interests. Scher is a scientific advisory board member of venture capital firm ProQuest, which owns an 8.3% stake in Novacea, a company that was developing a competing prostate cancer drug, Asentar™. Scher also happens to be the lead investigator in Asentar trials.

Curiouser still, an alleged power struggle over the regulatory jurisdiction of cancer vaccines between the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation Research (CBER) has thrown the actions of FDA officials under scrutiny. When Scher and two others sent FDA letters critical of Provenge, these letters were not only mysteriously ‘leaked’ to

an industry newsletter, The Cancer Letter, but also supposedly ghost written by someone inside CDER. And during the advisory committee meeting itself, after four panel members had answered “no” when asked whether there was evidence of Provenge’s “outright effectiveness” (CDER’s preferred wording), CBER director Jesse Goodman changed the phrasing to ask whether there was “substantial evidence” of effectiveness. With the revised wording, the panel voted 13 to 4 in favor of efficacy (the vote for safety was 17 to 0 in favor).

Efficacy is key here because in both Dendreon trials presented to FDA, Provenge failed to meet its primary endpoints. In certain respects, Dendreon shot itself in the foot by setting an over-optimistic efficacy expectation/hazard ratio for the trial of 0.585, which no conventional drug or chemotherapeutic has ever achieved in a comparable setting of late-stage disease. At the same time, however, Provenge did extend median overall survival by 4.5 months, and after 3 years, 34% of the men re-

ceiving therapy were still alive, compared with only 11% receiving placebo.

Thus, the trial was not designed to demonstrate survival advantages, but reanalysis showed that it did. Is it right that the FDA should ignore this? In the real world, in a scientifically assessable way, Dendreon’s under-powered trials do show real efficacious value, despite clear deficiencies in trial design and execution. And when the sole therapy available to end-stage prostate cancer patients is Taxotere® (docetaxel)—which extends survival by only 2.5 months and is so toxic it kills 300 patients itself every year—it is easy to understand why patients feel the data were strong enough. And it seems the advisory committee thought so, too.

FDA is, of course, perfectly within its rights to ignore all advice, but it is rare that it does so. The last known case where it overruled an advisory panel recommendation was the

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Us TOO Increases Minority Cancer Awareness

In honor of National Minority Cancer Awareness Week, held April 13-19, 2008, Us TOO is making available a new *SEA Blue* campaign poster highlighting prostate cancer awareness for African American men. African American men have the highest rate of prostate cancer incidence in the United States, and Us TOO wants to help spread the word so men and their families can get informed to protect themselves.

Posters can be obtained by chapters, physician’s offices and individuals by contacting the Us TOO office at 800-808-7866 or <ustoo@ustoo.org>.

As Men, Cancer Affects Us TOO
African-American men have the highest rate of prostate cancer incidence in the U.S.

Don't let prostate cancer catch you off guard...
You have much more living to do.

Us TOO is here for
Support, Education, Advocacy.

Bring life to the SEA BLUE Campaign.

- The week of April 13 - 19, 2008 is "National Minority Cancer Awareness Week"
- Share your stories. Spread the word about prostate cancer.
- Get informed. Save someone's life.

Contact Us TOO or your local chapter today.

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SEA BLUE
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As pink is to breast cancer,
blue is to prostate cancer.

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CELL GENESYS' TRIALS

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we can currently estimate that we will reach the required number of events needed to conduct the final analysis in the second half of 2009."

VITAL-1 is a multi-center, randomized, controlled Phase 3 clinical trial designed to compare GVAX cancer immunotherapy to Taxotere® (docetaxel) chemotherapy plus prednisone in hormone refractory prostate cancer (HRPC) patients with metastatic disease who are asymptomatic with respect to cancer-related pain. The primary trial endpoint is an improvement in survival. VITAL-1 was initiated in July 2004 and completed recruitment of 626 patients in July 2007. Patients were enrolled at approximately 130 sites in North America and Europe.

The company's second Phase 3 trial, VITAL-2, is a multi-center, randomized, controlled Phase 3 clinical trial designed to evaluate the safety and efficacy of GVAX immunotherapy for prostate cancer used in combination with Taxotere chemotherapy compared to the use of Taxotere chemotherapy and prednisone in HRPC patients with metastatic disease who are symptomatic with cancer-related pain. The primary endpoint of the trial is also an improvement in survival. VITAL-2 was initiated in June 2005 and is currently enrolling patients at approximately 90 sites in North America and Europe. The company expects to complete enrollment of approximately 600 patients in the first half of 2009 and if this is achieved, to have a sufficient number of events for a pre-planned interim analysis at that time.

The U.S. Food and Drug Administration (FDA) granted Cell Genesys Special Protocol Assessments (SPAs) for both VITAL-1 and VITAL-2. The SPA is a process that allows for official FDA evaluation of a Phase 3 clinical trial and provides trial sponsors with a binding written agreement that the design and analysis of the study are adequate to support a license application submission if that study is performed according to the SPA. Cell Genesys completed the modifications requested by FDA during the review process.

PRNewswire-FirstCall, 14 January 2008

PARTICIPANTS IN PHASE 1 ONCOLOGY TRIALS NOT VULNERABLE

Because phase 1 oncology trials are typically carried out in patients who are in advanced stages of disease and investigate untried therapies, they offer a relatively low prospect of clinical benefit with the potential for serious risks. Hence, they have been cited as "paradigmatic examples of research that exploits vulnerable persons," and critics of these trials have called for special safeguards to be put in place.

However, a study of the demographics and health-status characteristics of individuals who participate in phase 1 oncology trials in the United States showed that they are not a conventional vulnerable population, say a team from the department of bioethics at the National Institutes of Health in Bethesda, Maryland.

In the January 14 issue of the Archives of Internal Medicine (Arch Intern Med Vol. 168, pp. 16-20, 2008), the team reports the results of a review of 9841 people who participated in phase 1 oncology trials sponsored by the Cancer Therapy Evaluation Program between 1991 and 2002. These participants were predominantly white, middle-aged, and well educated. They were also likely to have private insurance, good performance status, and have already had their cancer treated before being approached to enroll in a phase 1 trial. Hence, there is little reason to assume that, as a group, these individuals have a compromised ability to understand information or to make informed and voluntary decisions, Christine Grady, RN, PhD, and colleagues conclude.

These trials do carry a big risk with relatively little benefit, the team acknowledged. In oncology, about 25% of these studies are testing a product that is being used in humans for the first time, and about 0.5% of participants die as a result of toxic effects, they point out. There are also data to suggest that tumor responses are seen in only 4% to 6% of participants, although a recent study suggested that the overall tumor response rates are higher than previously reported, at 10.6%. Hence, commentators have argued that participants are vulnerable.

Dr. Grady and colleagues take issue with this. They agree that phase 1 trial participants have serious disease and limited treatment options, which can constrain their decisions about research participation. But they point out that, as a group, these participants do not lack the cognitive capacity to make decisions and do not have general constraints on their personal liberties and voluntary decision making, although this might apply to particular individuals.

The team also disagrees with claims that patients with end-stage cancer are particularly vulnerable to exploitation by researchers. "Even extraordinarily difficult life decisions in trying circumstances can be made autonomously and rationally," they write. "Having few choices does not necessarily render one incapable of making a choice."

"Although individuals with end-stage cancer are influenced by the effects of ill health on their lives, they may still be quite capable of protecting their own interests and making rational informed choices, including those about research participation," Dr. Grady and colleagues write.

Medscape Medical News, 16 January 2008

EXPERIMENTAL DRUGS

(Continued from page 1)

with no remaining treatment options to fight for their own lives." The FDA said the appeals court was correct and in line with other rulings "that have rejected constitutionally based demands for access to unapproved investigational drugs."

The full U.S. Court of Appeals for the District of Columbia Circuit ruled against the alliance after a smaller panel of the same court held that terminally ill patients may not be denied access to potentially lifesaving drugs. The court said patients can access experimental drugs in certain situations and suggested Congress could change the law to broaden such access.

The case is Abigail Alliance v. Eschenbach, 07-444.

Yahoo! NEWS (AP), 14 January 2008

CANCER DOCTORS MAY NEED TRAINING ON EMPATHY SKILLS

Cancer specialists (oncologists) may need additional training to encourage patients to express their concerns and negative emotions and to respond empathically to these concerns, researchers recommended in a study published December 20, 2007, in the *Journal of Clinical Oncology* (*J Clin Oncol* Vol. 25, pp.5748-52, 2007).

The report presented data from the Studying Communication in Oncologist-Patient Encounters (SCOPE) project, an NCI-funded, three-site study from Duke University, the Durham Veterans Affairs Medical Center, and the University of Pittsburgh. It is based on results from 398 clinic conversations between 51 oncologists and 270 patients with advanced cancer. The study found that the oncologists encountered few empathic opportunities during their patient meetings (37 percent of visits) and responded with empathic statements infrequently (only 22 percent of the time).

Empathic responses are important in cancer care because "patients have less anxiety and depression and report greater satisfaction and adherence to therapy," the researchers noted. The study found that female patients were more likely to disclose painful emotions to female oncologists. In addition, younger oncologists and those who rated their orientation as more socioemotional than technical were more likely to respond with empathic statements.

"Oncologists and patients need to work to create an alliance conducive to patients expressing their emotions," the researchers suggested. Although the oncologists expressed high levels of confidence in addressing emotions, they may need more training to recognize emotions and to learn how to respond to patient concerns. "Many empathic opportunities were indirect and patients may be more satisfied if they can learn how to express their emotions more directly so that oncologists can respond appropriately," the authors noted.

NCI Cancer Bulletin, 8 January 2008

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

"High-fructose corn syrup (HFCS) is responsible for the American obesity epidemic? Really? So, when did you last see the Loch Ness Monster or Big Foot?"

Mark A. Moyad, MD, MPH

University of Michigan Medical Center, Department of Urology

*To order Dr. Moyad's new "No Bogus Science Diet Book" just call toll-free 1-877-722-2264 to reserve a copy now!

Bottom Line: High-fructose corn syrup (HFCS) is not as bad for your health as any other product that has an equal number of calories, but there are just a lot of B.S. "experts" out there that want to convince you that it is the reason for our obesity epidemic.

A popular theory as to why there is an obesity epidemic has been the replacement of table sugar with high-fructose corn syrup, but this does not seem to be a strong causative factor after this clinical trial. Research has yet to demonstrate whether beverages sweetened with high fructose corn syrup (HFCS) are healthier in terms of weight gain, compared to other beverages that have a similar caloric content. So this study set out to determine the impact of HFCS, table sugar, or milk on appetite and measurements of weight gain.

A total of 35 men and 35 women (n=70) with a normal body mass index (BMI) were utilized for this preliminary clinical trial.¹ After consuming a beverage of equal calories from a beverage with HFCS, table sugar, and milk a variety of weight gaining parameters were assessed. No significant differences were noted between the beverages. No differences were found in terms of a hunger response, insulin, glucose and other hormonal measurement of appetite control. Therefore, appetite and obesity blood measurements were not impacted by a variety of beverages that contain equal amounts of calories.

Monday morning quarterbacks are everywhere! Theories of why an obesity epidemic is occurring around world can be found everywhere. One of the more popular untested alternative medicine theories is that HFCS was created by humans and introduced in the food supply in the 1970s to slightly increase the fructose (55% compared to about 50% in table sugar)

content of products compared to table sugar (equal fructose and glucose content) and this apparently stimulated more appetite and belly fat accumulation. The problem with this simplistic theory is that it ignores the fact that the US food supply of HFCS content remained mostly unchanged over the past 15 years and that HFCS replaced table sugar for the most part and was not added to table sugar so basically you just substitute an equal number of calories. HFCS and sugar still contain 4 calories per gram of carbohydrate, so regardless of what product is used the caloric contribution is approximately the same.

It is time to recognize that the increasing overall caloric intake and decreasing overall physical activity in general has the most scientific research as to why there is an obesity epidemic. I wish I could blame my weight gain on HFCS or what they put into my diet cola over the past few years! The HFCS theory now belongs in the same location in the ridiculous conspiracy filing cabinet as these past wonderful contributions to history: Gunmen on the Grassy Knoll (no one was there except a boy holding an ice cream cone); Big Foot lives in Michigan's upper peninsula (just a hairy unshaven man...there are a lot of them in Michigan); UFOs landing in cornfields (we know this was just the bored kids of the land/farm owner); Loch Ness Monster photo (just a big guy in a funny looking bathing suit (have you been to certain parts of Florida lately...enough said); and my dad knows how to start his car my whispering the car's name (he had an automatic starter device placed in his car and the remote control device was in his coat pocket and I did not figure this one out 'til years later, and hey - isn't that a form of child abuse?!)

Reference

1. *Am J Clin Nutr* 86: 1586-1594, 2007.

NEWS FROM SOUTHWEST ONCOLOGY GROUP (SWOG)

Editor's Note: In 2007, Us TOO Medical Advisor Dr. E. David Crawford urged Us TOO to become more involved in SWOG and invited Us TOO President/CEO Tom Kirk to attend, exhibit and present.

Us TOO International attended the May and October 2007 SWOG meetings. Following that, Us TOO and key SWOG leadership met to collaborate and build a working relationship. Key Genitourinary (GU) SWOG leaders attended, including Drs. E. David Crawford (GU Committee Chair), Maha H.A. Hussain (GU Advanced Prostate Organ Site Chair), Ian Thompson, Jr. (GU Local Prostate Organ Site Chair) and Jennifer Scott (GU Protocol Coordinator, SWOG Operations Office). The appearance of this article is an initial step.

SWOG is one of the largest cancer clinical trials cooperative groups in the United States. Funded by research grants from the National Cancer Institute (NCI), part of the National Institutes of Health, the Group conducts clinical trials to prevent and treat cancer, and to improve the quality of life for cancer survivors. The Group celebrated its 50th anniversary during the Fall 2006 SWOG Meeting in Seattle.

SWOG studies many adult cancer types, including breast, gastrointestinal, genitourinary, gynecologic, and lung cancers, as well as melanoma, myeloma, leukemia and lymphoma. Approximately 120 clinical trials are underway at any given time.

SWOG's network of more than 5,000 physician-researchers, practice at nearly 550 institutions. Among SWOG's institutions are 17 of the NCI's 61 designated cancer centers. Physicians must meet strict medical and ethical requirements in order to become members of SWOG and to conduct the Group's protocols. Among the types of medical practices represented in SWOG are university teaching hospitals, community hospitals, community-based physician cooperatives and individual physician offices.

More than 7,000 cancer patients and healthy participants are enrolled each year in SWOG studies, and approximately 35,000 more are involved annually in ongoing clinical trials. Dur-

ing the last 25 years, more than 170,000 patients have directly benefited from the Group's trials, while millions more have received improved care as new standards of treatment or prevention are developed by SWOG.

Genitourinary Cancer Committee

The Genitourinary Cancer Committee of SWOG is a strong, multi-disciplinary committee that has made significant contributions to clinical research and has influenced patterns of clinical management throughout the world. The Committee focuses on improving survival and the quality of life of patients with genitourinary cancers while investigating novel biologically based therapy.

Current Open SWOG Prostate Cancer Clinical Trials:

Advanced Prostate

SWOG-9346 - Phase III Intergroup - Intermittent Androgen Deprivation in Patients with Stage D2 Prostate Cancer, Phase III

S0354 - Phase II - A Phase II Study of CNTO 328, A Monoclonal Antibody Against Interleukin-6 (IL-6) in Patients with Hormone Refractory Prostate Cancer

S0421 - Phase III Intergroup - Phase III Study of Docetaxel and Atrasentan versus Docetaxel and Placebo for Patients with Advanced Hormone Refractory Prostate Cancer

CTSU/C90202 - Phase III Intergroup - A Randomized Double-Blind, Placebo-Controlled Phase III Study of Early Versus Standard Zoledronic Acid to Prevent Skeletal Related Events in Men with Prostate Cancer Metastatic to Bone

CTSU/MDA-3410 - Phase III Intergroup - A Prospective Randomized Phase III Trial Comparing Consolidation Therapy with or without Strontium-89 Following Induction Chemotherapy in Androgen-Independent Prostate Cancer

Local Prostate

CTSU/C90203 - Phase III Intergroup - A Randomized Phase III Study of Neo-Adjuvant Docetaxel and Androgen Deprivation Prior to Radical Prostatectomy versus Immediate Radical Prostatectomy in Patients with

High-Risk, Clinically Localized Prostate Cancer

CTSU/R0415 - Phase III Intergroup - A Phase III Randomized Study of Hypofractionated 3D-CRT/IMRT versus Conventionally Fractionated 3D-CRT/IMRT in Patients with Favorable-Risk Prostate Cancer

CTSU/R0521 - Phase III Intergroup - A Phase III Protocol of Androgen Suppression (AS) and 3DCRT/IMRT vs AS and 3DCRT/IMRT Followed by Chemotherapy with Docetaxel and Prednisone for Localized, High-Risk Prostate Cancer

PR11 - Phase III Intergroup - A Phase III Study of Active Surveillance Therapy against Radical Treatment in Patients Diagnosed with Favorable Risk Prostate Cancer (START)

For more information on the Southwest Oncology Group, please visit their website <<http://swog.org>>.

CO-MORBIDITIES MAY LIMIT BENEFITS OF COMBINATION PROSTATE THERAPY

The addition of androgen suppression therapy (AST) to radiation therapy (RT) improved overall survival in men with localized prostate cancer and risk factors for disease recurrence, but the survival benefit may apply only to men who do not have moderate to high levels of other illnesses, researchers report in the January 23, 2008 issue of the Journal of the American Medical Association.

Previous observational studies and pooled analyses of randomized trials have suggested that AST may be associated with an increased risk of heart attacks and other cardiovascular events in older men.

In the current study, researchers randomly assigned 206 men with localized prostate cancer and a high risk of recurrence to either RT alone or RT plus AST for 6 months. The men, whose average age was 72.5, were classified into subgroups based on the severity of their other illnesses, such as diabetes or a previous heart attack.

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NEW NCI CLINICAL TRIAL STRESS MANAGEMENT THERAPY FOR

CHEMOTHERAPY PATIENTS

Name of the Trial: Randomized Study of Stress Management Therapy in Patients Undergoing Chemotherapy for Cancer (MCC-0501). See the protocol summary at <www.cancer.gov/clinicaltrials/MCC-0501>.

Principal Investigators: Dr. Teletia Taylor, Howard University, and Dr. Susan McMillan, University of South Florida

Why This Trial Is Important: Undergoing treatment for cancer may be one of life's most stressful experiences. Patients scheduled for chemotherapy may wonder how they will deal with its well-known side effects, such as nausea, vomiting, hair loss, and fatigue. These and other uncertainties can lead to overwhelming stress, which can reduce a patient's quality of life and, possibly, interfere with their recovery.

In this study, patients with newly diagnosed cancer who are scheduled to undergo chemotherapy will be randomly assigned to one of two groups. One group will receive standard psychosocial care along with stress management training, while the other will receive standard psychosocial care alone. The self-administered training will consist of multimedia information and instructions about three stress management techniques: progressive muscle relaxation and guided imagery, abdominal breathing, and coping skills.

Hispanic/Latino patients reportedly experience a disproportionately higher level of suffering from cancer and treatment-related stress. This is due, in part, to a lack of culturally relevant resources in Spanish. This study uses culturally sensitive self-education tools in both English and Spanish that are linguistically appropriate and incorporate Hispanic/Latino cultural beliefs.

"The adverse effects of chemotherapy on quality of life are well documented," said Dr. Taylor. "Stress management techniques have been shown to have beneficial effects on nausea,

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THE DOCTOR'S NOTE: COMMENTARY ON SELECTED ARTICLES IN THIS MONTH'S *HOTSHEET*

By Gerald W. Chodak, MD

An article from the National Cancer Institute about an ongoing study to determine if stress management therapy in patients receiving chemotherapy will improve quality of life is looking to recruit patients. According to the entry requirements from the website patients must have a new diagnosis rather than a progression of their disease to metastases. Nevertheless, patients might consider visiting the website for clarification <www.cancer.gov/clinicaltrials/MCC-0501>.

Another article from SWOG about ongoing clinical studies in prostate cancer is worth noting because in the United States, most physicians treating prostate cancer neither conduct clinical trials nor make their patients aware of a study for which they may be a good candidate. Consequently, all patients need to do this research themselves. If you have prostate or any other cancer, keep checking this website, <<http://swog.org>>.

Participation in clinical trials is the focus of another article regarding those individuals who participate in phase I studies. Are they being exploited because they are vulnerable?

This study found data against exploitation. The issue is important because only through controlled studies can progress be made. For the individual with an advanced cancer who has failed conventional therapy, what options are there?

The only way to receive a drug with some potential benefit is to participate in one of these trials and although the odds of benefit are small, they are not zero. As long as participants are completely informed of the risks, offering them an opportunity to participate is hardly exploitation and even doctors not involved in those trials should encourage it. Only after a phase I

study is completed, will a phase II and possibly a phase III study be possible.

The last article of interest suggests that cancer doctors may lack skills in being empathetic with their cancer patients. I have heard this complaint all too often and I do believe that this area of training but insufficient in our medical curriculum. If you are having difficulty coping with your disease, then don't hesitate to discuss it with your doctor and if you find that doctor lacking then an open discussion about it might be good for both of you!

CO-MORBIDITIES

(Continued from page 6)

After 7.6 years median follow-up, estimated 8-year survival was 74 percent for men randomized to RT plus AST compared with 61 percent for men assigned to RT alone. A total of 74 men had died – 44 of those assigned to RT alone and 30 assigned to RT plus AST.

Among the 157 men with only minor co-morbidities, 31 of those treated with RT alone had died compared with 11 of those in the RT plus AST group. Among the 49 men with moderate to severe co-morbidities, however, 19 of those randomized to RT plus AST had died, compared with 13 of those assigned to RT alone.

"Preexisting co-morbid illness may increase the negative effects of specific anticancer treatments such as AST," conclude the researchers, who were led by Dr. Anthony V. D'Amico of Brigham and Women's Hospital in Boston MA. They recommend that follow-up clinical trials be designed to further assess this interaction and identify which illnesses in particular may shorten life expectancy among men undergoing treatment with AST.

NCI Cancer Bulletin, 22 January 2008

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PROVENGE

(Continued from page 3)

‘morning after’ contraceptive Plan B. In that instance, the agency was roundly criticized for choosing political expediency over science.

In the case of Provenge, equivocal trial data and malpractice tittle-tattle have created a fog of uncertainty that provides little guidance of any kind to anyone. It may not be within the FDA’s statutory remit to orientate clinicians and biotech companies, but the fact is agency decisions do have that effect. And, at present, FDA appears to have neglected its role in guidance because of a knee-jerk defensive response to accusations of process impropriety.

At the very least, FDA should now explain its decision. Those developing other cancer vaccines would welcome the clarity. And prostate cancer patients, denied access to a potentially life-preserving therapy, deserve an answer. Anything less and confidence in the agency’s competence to regulate similar experimental cancer therapies could be seriously compromised.

Nature Biotechnology, Vol. 26, p. 1, January 2008

STRESS MANAGEMENT

(Continued from page 7)

vomiting, and emotional distress before the administration of chemotherapy as well as in the days following chemotherapy.

“The primary objective of this study is to determine whether a self-administered stress management intervention, previously found to be beneficial to primarily non-Hispanic chemotherapy patients in a single clinical setting, is effective in improving quality of life and decreasing psychological distress (anxiety and depression) in Hispanic and non-Hispanic patients receiving cancer chemotherapy in multiple community clinical settings. We have met our accrual target for non-Hispanics, so the trial is now open only to Hispanic patients,” Dr. Taylor added.

For More Information

To see the lists of eligibility criteria and study sites, go to <www.cancer.gov/clinicaltrials/MCC-0501> or call the NCI’s Cancer Information Service at 1-800-4-CANCER (1-800-422-6237). The toll-free call is confidential.

NCI Cancer Bulletin, 8 January 2008

ANDROGENS AND CANCER

(Continued from page 2)

“obliges the scientific community to move past a seductive, clinically relevant, and biologically plausible hypothesis and get on with the difficult task of exploring, analyzing, and characterizing modifiable risk factors for prostate cancer.” However, the question of where to go from here will take some serious discussion and debate, Dr. Godley commented to Medscape Oncology.

This finding will probably not affect the use of finasteride for prostate cancer prevention, even though it undermines part of the rationale for its use, Dr. Godley commented to Medscape Oncology. “I’m not sure that finasteride is being used much for that purpose anyway.” In addition, the theory is a little different in each of these 2 trials, he pointed out. The current study set out to investigate whether high androgen levels increase the risk for prostate cancer, and showed that they do not, whereas the finasteride trial set out to determine whether lowering androgen levels reduces the risk for prostate cancer, and showed that it did.

Medscape, 29 January 2008

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