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Us TOO® PROSTATE CANCER EDUCATION & SUPPORT

HOT SHEET

JULY 2004

MEDICARE AND YOUR PROSTATE CANCER TREATMENT: TAKE TIME TO TALK WITH YOUR PHYSICIAN

By Dr. Mark Moyad, MD, MPH

Medicare reform – it's the topic on everyone's minds these days, as the first changes from the historic Medicare Prescription Drug and Modernization Act passed last year take effect. For many patients, the most immediate change has to do with drug discount cards, but for cancer patients, payments for cancer and other drugs given in a doctor's office have changed and those changes are already being felt.

For cancer patients, the new law instituted lower co-pays effective in 2004. Recent estimates suggest that those co-pays may be cut even further next year, perhaps by as much as 50 percent on certain drugs. That's good news for patients, with the potential to be followed by even better news next year.

Unfortunately, as with most things, nothing is ever perfect. A loophole in the law that changed the co-pays is causing some concern in the cancer community. The transition to these new reimbursement rates creates an opportunity for doctors to make more money on certain cancer therapies.

(continued on page 6)

PROSTATE CANCER TAKES CENTER STAGE AT 2004 ASCO MEETING

The 2004 Annual Meeting of the American Society of Clinical Oncology in New Orleans had a great focus on Prostate Cancer with no less than 160 papers, posters and educational programs dealing with the disease.

In this month's HOT SHEET we will provide an overview of the abstracts and highlight several which may signal a shift in the way Prostate Cancer is treated in the future.

ASCO AMERICAN SOCIETY OF CLINICAL ONCOLOGY

Perhaps the 'biggest news' of the conference was the release of results from a number of studies detailing the benefit of a well known Chemotherapy agent : Taxotere. For the first time the use of a chemotherapy agent in the treatement of prostate cancer shows a measurable survival benefit.

Some have already discounted the results - which indicated a 3 month survival benefit in men with advanced / androgen-independent prostate cancer. But it is a starting point for future research - and on top of survival there were also quality of life and PSA drop advantages.

ASCO Highlights begin on Page 2.

IMPROVING PROSTATE CANCER SURVIVAL

By Stacie Overton
Ivanhoe Health

New research may help extend the survival for men with advanced prostate cancer. The findings of two new studies were presented at this year's annual meeting of the American Society of Clinical Oncology in New Orleans.

In the first study, researchers from the Southwest Oncology Group studied more than 600 men with hormone-refractory prostate cancer. About half of the men were treated with the drug combination docetaxel and estramustine while the other half was treated with standard care, which is mitoxantrone and prednisone.

In that study, Daniel Petrylak, M.D., from Columbia University in New York and colleagues found improved survival among the men who received the docetaxel/estramustine treatment. He says, "Survival was significantly greater. Men in the docetaxel/ estramustine group had about a 20-percent reduced risk of death." He adds: "This shows docetaxel can effectively treat [this type of] prostate cancer. It's now a treatment to build upon."

Side effects included nausea,

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US TOO PUBLICATIONS

In addition to the Hot Sheet, ***Us TOO*** also publishes a FREE e-mail based news service 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

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40 Years of Quality Cancer Care
ASCO 2004 ANNUAL MEETING

Highlights from the 2004 ASCO Annual Meeting

ASCO RELEASES GUIDELINE ON TREATMENT OF ANDROGEN-SENSITIVE PROSTATE CANCER

ASCO today released its most recent Clinical Practice Guideline, "American Society of Clinical Oncology Recommendation for the Initial Hormonal Management of Androgen-Sensitive Metastatic, Recurrent, or Progressive Prostate Cancer." The guideline is available on the ASCO website (ASCO.org).

"The guide asks the question: 'When should hormone therapy be started?'" said Andrew Loblaw, MD, of the Toronto Sunnybrook Regional Cancer Centre, lead author of the guideline. "Hormone therapy has a host of negative side effects. A doctor may be doing men a disservice by starting hormone therapy too early."

The ASCO Expert Panel developed these recommendations based on a review of 16 randomized controlled trials and systematic reviews. One recommendation the group formulated was that the use of nonsteroidal antiandrogens can be considered as an alternative to orchiectomy or treatment with luteinizing hormone-releasing hormone (LHRH) agonists (medical castration).

Both orchicetomy and treatment with LHRH agonists reduce production of testosterone. However, nonsteroidal antiandrogens, most often administered orally, have been shown to be associated with the same survival rates as those for both therapies, but with fewer side effects, particularly a lessened impact on the patient's libido.

The expert panel also recommends that for men who seek a more aggressive approach, physicians should discuss the option of combined androgen blockage (CAB) treatment, which involves the use of nonsteroidal antiandrogen therapy and orchiectomy or LHRH analogs to give a more complete inhibition of male hormones. CAB treatment may result in a small improvement in survival compared with orchiectomy or LHRH analogs alone.

The guideline encourages physicians to talk about treatment options with their patients, including the timing of treatment. There is much debate in the oncology community about the best time to begin treatment: once the prostate cancer has advanced based on a rising prostate-specific antigen (PSA) level (early deprivation therapy) or when symptoms become evident (deferred deprivation therapy). No studies have shown a survival advantage for starting treatment early, especially considering the side effects of the treatments.

"The aggressiveness of the cancer in relation to the potential side effects must be factored into the equation by both patients who are considering a particular therapy and physicians who are recommending it," said Howard Scher, MD, of Memorial Sloan-Kettering Cancer Center. "This is straightforward for patients with symptoms. In contrast, the risk/reward ratio is more difficult to estimate for patients without symptoms who have rising PSA levels indicating progressive disease."

To prevent disease from becoming hormone refractory, hormone therapy can be delivered for specified periods and then discontinued temporarily

according to a schedule. It has been proposed that such "intermittent hormone therapy" may maintain hormone responsiveness for longer than standard continuous hormone treatment and have fewer side effects. However, this concept is currently being tested in randomized clinical trials and is still considered experimental. Physicians are encouraged to discuss participation in a clinical trial with men who are interested in intermittent hormone therapy.

A new patient guide based on the latest Clinical Practice Guideline, Hormone Therapy for Advanced Prostate Cancer, is available on the People Living With Cancer website (www.plwc.org).

SURVIVAL DATA INDICATING DOCETAXEL FOR FIRST-LINE TREATMENT OF ANDROGEN-INDEPENDENT PROSTATE CANCER

Data indicating a significant survival benefit from two regimens of docetaxel-based chemotherapy compared with the current standard treatment for androgen-independent prostate cancer was presented in a Plenary Session. The results from these trials were determining factors in a U.S. Food and Drug Administration (FDA) announcement on May 19, 2004, approving docetaxel in combination with prednisone as first-line therapy for this indication.

A three-arm multicenter phase III trial to compare docetaxel plus prednisone with mitoxantrone enrolled 1,006 men with hormone-refractory prostate cancer (abstract #4), many of whom had previously received two or more cycles of hormone therapy. After random assignment to treatment with docetaxel on either of two dosing schedules or to mitoxantrone, all coupled with prednisone, the combined median survival rate for the two schedules of docetaxel was 18 months compared with 17 months for mitoxantrone. However, the median survival for patients taking docetaxel at a dosage of 75 mg/m2 every three weeks for 10 cycles was 19 months (hazard ratio = 0.76). Both pain and prostate-specific antigen (PSA) responses were significantly improved with docetaxel. The three-week schedule of docetaxel was associated with a higher incidence of grade 3 and 4 neutropenia than was standard therapy.

Supporting data for the FDA approval of docetaxel-based regimens for the treatment of androgen-independent prostate cancer appear in a second trial involving 770 eligible men (abstract #3). In this trial, the median survival for patients treated with docetaxel plus estramustine was 18 months compared with 15 months for men taking mitoxantrone plus prednisone (log rank p = 0.008; hazard ratio, 0.77). Docetaxel was also associated with a six-month median time to progression compared with three months for standard treatment ($p < 0.0001$). Although there was no significant difference in therapy-related toxic deaths, grade 3 and 4 adverse effects were significantly more common with docetaxel, due principally to higher rates of gastrointestinal and cardiovascular toxicity.

Bruce J. Roth, MD, of Vanderbilt-Ingram Cancer Center, served as discussant of these two presentations. Dr. Roth noted patterns-of-care data indicating that only about half of men with hormone-independent prostate cancer are treated with chemotherapy at a point of disease progression at which they might enjoy a survival benefit. Currently, many of these men undergo multiple courses of hormone therapy with no apparent survival benefit. "With the demonstration of significantly improved survival with docetaxel-based chemotherapy, and with the FDA's approval of the docetaxel plus prednisone regimen," Dr. Roth said, "many more men may undergo timely chemotherapy as first-line treatment for this disease, with improved survival as a result." He added that the results of these two trials should "dispel the perception that men with advanced hormone-refractory prostate cancer are not candidates for first-line chemotherapy."

Mario A. Eisenberger, MD, of Johns Hopkins Medical Institutions, presented the trial summarized in abstract #4 on behalf of colleagues at 10 North American and European centers. Daniel P. Petrylak, MD, of New York Presbyterian Hospital and the Columbia University College of Physicians and Surgeons, presented the findings of the multicenter SWOG 99-16 trial (abstract #3).

Docetaxel is a tubulin-inhibiting taxoid antineoplastic agent that has previously been approved by the FDA for treatment of advanced lung and breast cancers. Each of the trials was designed and organized on the basis of prior encouraging antitumor activity demonstrated for docetaxel-based regimens in phase II trials involving patients with hormone-independent prostate cancer. In phase III trials of mitoxantrone plus prednisone, the median survival rate has ranged from 10 to 12 months.

EPOTHILONE B ANALOGUE EXHIBITS ANTINEOPLASTIC ACTIVITY IN PROSTATE CANCER

Two multicenter phase II trials reported that the investigational drug BMS-247550 (ixabepilone), a semi-synthetic analogue of epothilone B, has antineoplastic activity in patients with chemotherapy-naïve metastatic hormone-resistant prostate cancer. In one trial, BMS-247550 was the sole agent. The other trial compared this agent alone and in combination with estramustine phosphate with no significant difference in adverse events except for severity of thrombosis and nausea. In each study, the primary endpoint was a prostate-specific antigen (PSA) decrease of 50% or more with stability or regression of measurable disease.

In a trial conducted by the Southwest Oncology Group (SWOG) that was reported by Maha Hussain, MD, of the University of Michigan (abstract #4510), 41 men who had had either medical or surgical androgen ablation and who were chemotherapy naïve were treated with ixabepilone 40 mg/m2 administered intravenously over

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ASCO HIGHLIGHTS

(continued from page 3)

three hours every three weeks. Data for 22 evaluable patients indicated that the drug has antineoplastic activity in this disease based on nine PSA responses and three objective responses among 10 patients who had measurable disease at the time of enrollment. Eighty percent of patients who had experienced treatment-induced PSA responses had decreases of 70% or greater. The estimated one-year survival was 75%, and the median survival had not been reached at the time of analysis.

William K. Kelly, MD, of Memorial Sloan-Kettering Cancer Center, reported updated results from a randomized trial comparing single-agent ixabepilone with a regimen of ixabepilone plus estramustine phosphate in 92 chemotherapy-naïve patients with progressive castrate-metastatic prostate cancer (abstract #4509). Patients who received the combination therapy were also treated with daily anticoagulant therapy. Combination therapy resulted in PSA responses in almost 70% of patients, compared with 56% for monotherapy. Partial regression of measurable disease occurred in 44% and 23% of patients, respectively. There were 81 surviving patients at a median follow-up of seven months.

Although each of these trials successfully demonstrated the antineoplastic activity of ixabepilone in chemotherapy-naïve patients with hormone-refractory prostate cancer, the agent was associated with extensive toxicities. In the SWOG trial, treatment was discontinued for 29% of patients because of adverse hematologic (primarily neutropenia) and/or neurologic effects. There were no grade 4 or 5 toxicities other than hematologic. The toxicity profile was similar in the study presented by Dr. Kelly, except that the addition of estramustine led to more frequent nausea (grades 1 and 2). Both with and without estramustine, ixabepilone was associated with grade 1-3 neuropathy in more than half of patients.

When asked by Eric J. Small, MD, of the University of California, San Francisco, if further development of ixabepilone can be justified in light of its toxicity profile, Dr. Hussain responded that the future of this agent depends on "our learning to deal with the neurotoxicities." In contrast, Dr. Kelly noted that in his study, neuropathy associated with ixabepilone "was prominent but has proven manageable, though it requires further characterization." Daniel P. Petrylak, MD, of Columbia University challenged the justification of phase III trials of the ixabepilone/estramustine regimen due to the toxicity of estramustine in phase II trials. Dr. Kelly acknowledged the need for additional trial data on the efficacy and adverse effects of estramustine.

"Do the epothilones represent new therapy for prostate cancer or more of the same?" This provocative question introduced the discussion by George Wilding, MD, of the University of Wisconsin. BMS-247550 is a semi-synthetic analogue of epothilone B, which has been shown in preclinical studies to have activity against taxane-resistant and taxane-sensitive cell lines, and in clinical trials to have cytotoxic activity against a range of tumors both sensitive and resistant to taxanes. Like the taxanes, the epothilones are targeted at the mitotic spindle, where they induce microtubule stabilization resulting in mitotic arrest at the G2/M transition.

In light of these similarities, Dr. Wilding said, it is important to compare the epothilones with the taxanes with respect to both efficacy and toxicity in prostate cancer, except in those tumors that are resistant or refractory to taxanes. During the Plenary Session on Monday, two phase III taxane trials in androgen-independent prostate cancer were presented. One was a study by Dr. Petrylak utilizing taxotere plus estramustine compared with mitoxantrone plus prednisone (abstract #3). The second trial, reported by Mario A. Eisenberger, MD, of Johns Hopkins University, evalulates taxotere plus prednisone (abstract #4). The PSA and tumor-response data from those trials are similar to those reported by Dr. Hussain and Dr. Kelly.

Ideally, patients who have a response to epothilones would be different from those in whom the taxanes are efficacious, thus presenting two "activity realms" justifying–even requiring–parallel drug development. Regarding this point, Dr. Wilding referred to a phase IIa trial in which Epo-906 was selected as "an appropriate alternative to taxane therapy in patients with hormone-resistant prostate cancer" because "it is not a substrate for multidrug-resistance protein" (abstract #4563). This trial was presented at a Poster Discussion Session. In order to illustrate the differences among epothilones, Dr. Wilding pointed out that in that study, the primary toxicities were gastrointestinal rather than neurologic.

"Are there possible molecular predictors of response to epothilones that might differ from those for taxanes?" Dr. Wilding asked. There is some evidence that prostate tumor cells with mutated P53 genes may respond better to epothilones than those with wild-type P53. Additional findings may provide molecular bases for predicting which patients will have a better response to taxanes or to epothilones. In search of such markers, ECOG 3803 will address the issue of neoplastic activity in hormone-refractory prostate cancer utilizing another epothilone, BMS-550, in patients who are chemotherapy-naïve or have previously been treated with either mitoxantrone or taxanes. The trial design calls for identifying predictive values for response. In another effort to identify post-taxane therapeutic alternatives, a multicenter randomized trial organized by the Prostate Cancer Foundation involved treatment with either mitoxantrone or BMS-550 in patients for whom taxane therapy has failed.

Repeating his opening question, "Do the epothilones represent new therapy for prostate cancer or more of the same?" Dr. Wilding concluded that for today, the answer has to be "maybe." "Hopefully, tomorrow we will have sufficient molecular and clinical evidence on which to base a definitive answer."

ASCO PROSTATE CANCER HIGHLIGHTS

The Abstracts Identified By Number and Title Below Can Be Found on the ASCO Website (www.asco.org)

Docetaxel in combination for Hormone Refractory Prostate Cancer
Plenary Presentation

Plenary Discussant:
Bruce J. Roth, MD

3 SWOG 99-16: Randomized Phase III trial of docetaxel (D)/ estramustine (E) versus mitoxantrone(M)/prednisone(p) in men with androgen-independent prostate cancer (AIPCA)

4 A multicenter phase III comparison of docetaxel (D) + prednisone (P) and mitoxantrone (MTZ) + P in patients with hormone-refractory prostate cancer (HRPC)

Advances in Systemic Therapy for Prostate Cancer Eduction Session

Chemotherapy for Androgen-Independent Prostate Cancer
Tomasz Beer

Future Direction of Systemic Therapy for Prostate Cancer
Robert DiPaola

Neoadjuvant and Adjuvant Systemic Therapy in Rish-Risk Localized Prostate Cancer
William Oh

PSA Endpoints: How they will alter clinical practice

Oral Presentation Discussant: Judd W. Moul, MD

4503 The impact of a delay in initiating radiation therapy on prostate-specific antigen outcome for patients with clinically localized prostate cancer

4504 Does post-operative radiotherapy (P-RXT) after radical prostatectomy (Px) improve progression-free survival (PFS) in pT3N0 prostate cancer (PC)? (EORTC 22911)

4505 Three-month change in PSA as a surrogate endpoint for mortality in advanced hormone-refractory prostate cancer (HRPC): data from Southwest Oncology Group Study S9916.

4511 A reduction in the rate of PSA rise following chemotherapy in patients with metastatic hormone refractory prostate cancer (HRPC) predicts survival: Results of a pooled analysis of CALGB HRPC trials

Epothilones: A new tool for the treatment of advanced prostate cancer

Oral Presentation Discussant:
George Wilding, MD

4509 Multi-institutional trial of the epothilone B analogue BMS-247550 with or without estramustine phosphate (EMP) in patients with progressive castrate-metastatic prostate cancer (PCMPC): Updated results

4510 Epothilone B (Epo-B) analogue BMS-247550 (NSC #710428) administered every 21 days in patients (pts) with hormone refractory prostate cancer (HRPC). A Southwest Oncology Group Study (S0111).

Bone Complications of Prostate Cancer

Protecting skeletal integrity in prostate cancer patients
Oral Presentation Discussant:
Celestia Higano, MD

4511 Development of bone metastases from prostate cancer: first results of the MRC PR04 trial (ISCRTN 61384873)

4507 Association between androgen deprivation therapy and fracture risk: A population-based cohort study in men with non-metastatic prostate cancer

4508 Effects of Atrasentan on Disease Progression and Biological Markers in Men with Metastatic Hormone-Refractory Prostate Cancer: Phase 3 Study

Posters

4575 Continuing benefit of zoledronic acid for the prevention of skeletal complications in men with advanced prostate cancer

4576 Clinical benefit of zoledronic acid for the prevention of skeletal complications in patients with prostate cancer based on history of skeletal complications

8058 Zoledronic acid reduces the need for radiation to bone in patients with breast or prostate cancer metastatic to bone: a survival-adjusted cumulative incidence analysis

New approaches to predicting outcome in patients with prostate cancer

Poster Discussant:
William K Kelly, DO

4551 Is prostate-specific antigen a surrogate for survival in advanced prostate cancer?

4552 Duration of response to androgen deprivation therapy and survival after subsequent biochemical relapse in men initially treated with radical prostatectomy

4553 What is the Probability of a Positive Bone Scan (+BS) in Patients with a Rising PSA after Radical Prostatectomy (RP): A New Nomogram

4554 Prostate-Specific Antigen Doubling Time as a Predictor of Prostate Cancer Disease Progression and Survival

4555 Prostate specific antigen doubling time (PSADT) predicts for distant failure and prostate cancer specific survival (PCSS) in men with biochemical relapse after radical prostatectomy (RP

4556 Racial disparity of Epidermal Growth factor Receptor (EGFR) expression in prostate cancer (PC).

4557 Prognostic Significance of Plasma Chromogranin A Levels in Hormone-Refractory Prostate Cancer Patients Treated on Cancer and Leukemia Group B (CALGB) 9480

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MEDICARE AND YOUR PROSTATE CANCER

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Certainly the vast majority of doctors will act solely in the best interests of their patients, but the loophole may prompt some physicians to encourage patients to switch their cancer therapy / medication and perhaps switch back again when reimbursement changes again in 2005. While this might mean more money for the doctor in 2004, when the rates go down again in 2005, it could mean trouble for patients who end up on certain therapies – they could find themselves paying nearly double what they might pay in 2005, and with some therapies, it could be up to a year before anything can be done about it.

Certainly some patients will benefit from longer-term therapies and working with their doctors, they will be able to keep abreast of the changing co-pay rates to ensure their costs stay low. However other patients may be better suited for shorter-term therapy, for both medical and financial reasons. Shorter-term therapies can also provide the opportunity for ongoing discussion and monitoring of the patient's prostate cancer with his doctor at regular intervals.

The situation is likely to remain confusing for patients for the next two years as the reimbursement rate changes are fully implemented. So how can you be sure you have all the facts if your doctor recommends a switch in your prostate cancer treatment?

The most important thing to do is to remain alert to any suggestions of a change in treatment and talk to your doctor about them. Beware of treatment changes "in disguise" such as "your treatment now has a different name" or "we no longer stock the old treatment." Medications don't change names and your doctor can always order your existing treatment. Any suggestion should be accompanied by sound medical rationale.

Making sure you understand what your doctor or nurses are telling you is very important with respect to treatment decisions. When you are talking about treatment with your physician, be sure that you understand why he or she is recommending one treatment over another and what the implications of those treatment decisions may be. Ask questions when treatment changes are being recommended and progress is being reported. Make sure that any changes that are made are for reasons you understand and support, such as that your current treatment is not working for you or because you are experiencing side effects that could be lessened by a change in treatment.

TAKE THE OPPORTUNITY TO TALK WITH YOUR PHYSICIAN

To ensure you're prepared to talk about your treatment with your physician, consider the following list of questions as a guide:

For new treatments:

- Why are you recommending this medication? Why do you think it is best suited to my case?
- Are there alternatives to this approach? What are the pros and cons?
- What are the side effects associated with this treatment? How many patients experienced these side effects in clinical trials and/or in his/her experience?
- How will we monitor the success of this treatment?

When evaluating treatment progress:

- How well is my treatment working? What tests show progress?
- Are my results more or less than what you expected?
- Should we continue with this treatment given its results or should we consider a change?

When changing treatments:

- Why are you recommending switching to a new hormonal treatment? Is it due to a change in my condition or has my existing medication stopped working?
- How is this treatment different from my existing treatment plan?
- What are the side effects of this new treatment? How do they compare to my existing treatment?
- What impact will this treatment have on my insurance? coverage/co-pay, if any? Is cost a factor in the decision? Why?
- How will we monitor the success of this new treatment? What are the milestones?

Of course, these questions are simply a starting point for you to use and adapt to your own relationship with your doctor. The important thing to know is that it is your health and he or she is there to help you, so be prepared, but then don't be shy about taking time to make sure you understand what is going on.

ASCO HIGHLIGHTS

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58 Adrenal Androgen Levels Predict Response to Ketoconazole in Patients with Androgen Independent Prostate Cancer: Results from CALGB 9583

Redefining options for localized prostate cancer
Poster Discussant: Theodore DeWeese, MD

4566 Treatment "mismatch" in early prostate cancer: an empirical measure of patient-physician communication.

4567 Fifteen year follow up of the first cohort of localized prostate cancer patients treated with brachytherapy.

4568 A phase II study of external beam radiation therapy combined with permanent source brachytherapy for intermediate risk clinically localized adenocarcinoma of the prostate: Preliminary results of RTOG P-0019

4569 Prostate cancer treated with radiotherapy with or without androgen deprivation: the importance of the PSA nadir within 12 months

4570 Immediate hormonal therapy versus observation after radical prostatectomy and pelvic lymphadenectomy for node positive prostate cancer: At 10 years results of EST3886

4571 PSA Nadir and 24 Month Biopsy Interim Analysis of AdV-tk/ Valacyclovir Gene Therapy in Combination with Radiotherapy vs Radiotherapy Alone for Prostate Cancer

4572 A clinical trial of Virus-Directed Enzyme Prodrug Therapy (VDEPT) using adenovirus encoded nitroreductase (ntr) and CB1954 in patients with localized prostate cancer (PCa)

Advanced prostate cancer: How patient friendly is current therapy?
Poster Discussant: Nancy Ann Dawson, MD

4573 The Effect Of Race On Progression-Free Survival In Patients With Metastatic Hormone-Refractory Prostate Cancer (HRPC): A Pooled Analysis Of CALGB Studies

4574 Prognostic value of anemia in untreated metastatic prostate cancer: a multivariate analysis of SWOG 8894

4575 Continuing benefit of zoledronic acid for the prevention of skeletal complications in men with advanced prostate cancer

4576 Clinical benefit of zoledronic acid for the prevention of skeletal complications in patients with prostate cancer based on history of skeletal complications

4577 Need for awareness and monitoring of ocular toxicities (OT) due to weekly docetaxel administration: experience during a trial of neoadjuvant docetaxel (D) and mitoxantrone (M) for patients with high-risk prostate cancer (PC)

4578 The effect of hormonal therapy for prostate cancer on the electrocardiographic QT interval: Phase 3 results following treatment with leuprolide and goserelin, alone or with bicalutamide, and the GnRH antagonist abarelix

4579 Quality of Life (QOL) and Pain in Advanced Stage Prostate Cancer: Impact of Missing Data on Evaluating Palliation in SWOG 9916

8016 Pilot Evaluation of Paroxetine for Alleviation of Hot Flashes in Men

Expanding options for patients with metastatic prostate cancer
Poster Discussant: Naomi B. Haas,MD

4559 Efficacy Of Peripheral Androgen Blockade On Prostate Cancer: Results Of CALGB 9782

4560 Phase I Trial of Exogenous Testosterone (T) for the Treatment of Castrate Metastatic Prostate Cancer (PC)

4561 Randomized, Adaptive, Phase II Selection Trial of Four Chemotherapy Regimens in Androgen Independent Prostate Cancer (AIPC)

4562 High Activity Rhenium-186 Hydroxyethylidene Diphosphonate (HEDP) with Autologous Peripheral Blood Stem Cell (PBSC) Transplant-A Novel Treatment Strategy in Hormone Refractory Prostate Cancer Metastatic to Bone.

4563 A Phase IIa trial of weekly EPO906 in patients with hormone-refractory prostate cancer (HPRC)

4564 Response to second-line taxane-based therapy after first-line epothilone B analogue BMS-247550 (BMS) therapy in hormone refractory prostate cancer (HRPC)

4565 A Phase 2 Study of an Allogeneic GM-CSF Gene-Transduced Prostate Cancer Cell Line Vaccine in Patients with Metastatic Hormone-Refractory Prostate Cancer (HRPC)

2507 Vaccination of metastatic prostate cancer patients using mature dendritic cells transfected with mRNA encoding hTERT or an MHC class II targeted hTERT/LAMP fusion protein: Results From A Phase I Clinical Trial.

IMPROVING SURVIVAL

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vomiting and infections.

In a second study, researchers studied men with prostate cancer who received one of three treatments: docetaxel plus prednisone every week; a higher dose of docetaxel plus prednisone every three weeks, or mitoxantrone plus prednisone weekly.

Mario Eisenberger, M.D., from Johns Hopkins in Baltimore presented the research. He says survival among the men who received the docetaxel/ prednisone treatment every three weeks was significantly greater (18.9 months) than the other two treatment regimens (17.4 months and 16.5 months respectively). Results show there was also a greater drop in PSA level among men in this treatment group, as well as less pain and improved quality of life.

Dr. Eisenberger says, "It's a reason for celebration because we see a survival benefit, but it's also a reason for optimism because this is something we can build on."

RADIATION AFTER SURGERY HELPS PROSTATE CANCER PATIENTS LIVE LONGER

Prostate cancer patients who receive radiation therapy within six months after surgery live longer than patients who do not receive radiation afterwards, according to a new study in the July 1, 2004, issue of the International Journal of Radiation Oncology *Biology *Physics, the official journal of ASTRO, the American Society for Therapeutic Radiology and Oncology.

Between 1986 and 1999, 415 patients underwent surgery to remove their prostate and surrounding lymph nodes. The patients were then split into two groups - those who were scheduled for external beam radiation therapy within six months of surgery and those who would be followed over time and possibly undergo radiation therapy later if the cancer showed signs of returning. None of the patients showed any evidence of metastatic disease.

Within eight years, prostate specific antigen tests on the patients revealed that 69 percent of patients who received radiation therapy within six months of surgery showed no signs of the prostate cancer returning while 31 percent of patients who did not have radiation at all or had radiation after the cancer recurred. Researchers also found that the disease remained localized in the prostate for 93 percent of the patients in the radiation therapy group compared with 63 percent in the other. The risk of death from localized prostate cancer was also significantly lower in the radiation therapy group.

"To my knowledge, this is the largest study of its kind completed at a single institution," said Cesare Cozzarini, M.D., a radiation oncologist at San Raffaele H. Scientific Institute in Milan, Italy. "The results show that radiation therapy after surgery helps limit the chances that the cancer will recur allowing prostate patients to live longer."

For more information on radiation therapy for prostate cancer, please visit http://www.astro.org/patient/treatment_information/ for a free brochure.

MEN ON "WATCHFUL WAITING" ELIGIBLE FOR SOY-MUSHROOM EXTRACT TRIAL

Men who are on active surveillance or "watchful waiting" for prostate cancer may be eligible to enroll in a University of California (UC) Davis Cancer Center clinical trial of genistein concentrated polysaccharide, or GCP, a food extract derived from soybeans and shiitake mushrooms.

The new study builds on a preliminary trial, completed last year, that found GCP reduced levels of prostate-specific antigen in a small group of "watchful waiting" patients. GCP is used as a complementary therapy for prostate cancer in Japan, Korea and other parts of Asia.

"If we can find a chemopreventive agent capable of slowing or stopping the progression of early, localized prostate cancer, we'll have something to offer men besides watchful waiting," said Ralph deVere White, professor and chair of urology at UC Davis School of Medicine and Medical Center, director of the UC Davis Cancer Center and a principal investigator of the GCP trial. "It would be an important development in prostate cancer."

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