INSIDE THIS ISSUE

Us TOO® PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

February 2005

A Message From Us TOO President and CEO, Tom Kirk

I am repeating thoughts here in the Hotsheet which originally appeared in December's Us TOO Prostate Cancer *NEWS You Can Use* e-newsletters to once again highlight Prostate Pointers and its web-based support communities.

I wrote this after attending a moving and inspirational memorial service with my wife for a young women, who passed away from metastatic breast cancer. It reminds me of one of the articles we highlighted last edition in the *NEWS You Can Use* that states "A federal report on cancer rates shows prostate cancer is the leading cancer among U.S. men and breast cancer is the most common form seen in women."

During Sharon's service it was repeatedly clear that we need to embrace life and as she frequently said during her life "concentrate on love while we are here".

It was so clear once again that

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Changes To Medicare Payments For Cancer Drugs Affecting Delivery Of Prostate Cancer Therapies

The Medicare Prescription Drug and Modernization Act (MMA) included **major changes in Medicare payments for cancer therapies** and other drugs covered under Medicare and administered in physicians' offices.

Many health policymakers believed these payments exceeded providers' true drug costs, creating financial incentives for a physician to choose certain drugs based on reimbursement rates vs. patients' medical needs. Thus, as of January 1, 2005, drug payments will be based on a new Average Sales Price plus 6% formula.

However, there is a great deal of disagreement whether this new formula adequately covers the costs of administering cancer drugs. Thus, these changes could have an unintended, but very *negative impact*, on prostate cancer patients

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Lupron® Settlement Notification Begins

Consumers, insurers and health benefit plans are expected to share $150 million in compensation to settle lawsuits alleging drug companies fraudulently promoted the prescription medication Lupron.

A court-ordered program was announced Friday to notify parties eligible for compensation under a proposed settlement, scheduled to be considered by a federal judge April 13.

The settlement would cover parties who paid for Lupron from January 1, 1985 through March 31 of this year, according to an announcement by U.S. District Court in Boston. The class includes consumers who paid for any portion of the drug's cost, as well as insurers, employee welfare benefit plans and governmental employer plans.

The proposed $150 million payment would settle litigation against TAP Pharmaceutical Products Inc., Abbott Laboratories Inc. and Takeda Pharmaceutical Co. Ltd. Lawsuits alleged fraud involving

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US TOO PUBLICATIONS

In addition to the Hotsheet, Us TOO offers a FREE e-mail based service called *NEWS You Can Use* sponsored by Sanofi, 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.

Items contained in Us TOO publications are obtained from various news sources and edited for inclusion. Where available, a point-of-contact is provided

References to persons, companies, products or services are provided for information only and are not endorsements. Readers should conduct their own research into any person, company, product or service and consult with loved ones and personal physician before deciding on **any** course of action.

THE US TOO PROSTATE CANCER HOT SHEET IS MADE POSSIBLE BY A CHARITABLE CONTRIBUTION FROM

AstraZeneca

LUPRON SETTLEMENT

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the marketing, sale and distribution of Lupron that caused consumers and other parties to overpay.

Class members will be notified of their rights by mail and in newspaper and magazine advertisements before the hearing. Members can ask for a payment, to be excluded from or object to the settlement.

The deadline to file claims is May 15, 2005. A toll-free number, 1-866-410-7650, has been established in the case as well as a Web site, www.lupronclaims.com.

Associated Press, 7 January 2005

PRESIDENT'S MESSAGE

(Continued from page 1)

families, companions, friends and loved ones are so affected by cancer and Us TOO is an education and support network that remains the place to turn to for the latest information and support.

I want to urge people out there to "share their concerns and love" on Prostate Pointers on our website UsTOO.org. Prostate Pointers was developed by Nancy Peress and Gary Huckabay, who now serve as Us TOO consultants after NexCura donated Prostate Pointers to Us TOO during 2004.

Prostate Pointers has 14 moderated mailing lists and a bulletin board where you can ask questions and receive answers.

- **Physician-to-Patient** provides the opportunity to read focused discussion about clinical problems with prostate cancer.
- **The Circle** provides support for wives, families, friends, and significant others of men with prostate cancer and, of course, the men themselves.
- **Seed Pods** offers information and support to those interested in radioactive seed implant (brachytherapy) treatment.
- **Prostate Cancer and Intimacy** offers open and frank discussion about the problems with intimacy and prostate cancer.
- **Prostate Cancer Action Network** is for prostate cancer patients who want to concentrate their forces into a single voice.
- **RP** is for discussion and support for patients interested in *radical prostatectomy*.
- **Ice Balls** discusses cryosurgery as a prostate cancer treatment. This list is for patients, medical professionals, prostate cancer patients and family members--anyone with an interest in cryosurgery ablation for prostate cancer treatment.
- **CHB** is for discussion and support of combined hormonal blockade for prostate cancer.
- **EBRT** is for discussion and support for patients interested in external beam radiation therapy as a treatment for prostate cancer.
- **Promise** is a place for those grieving a loss and offers solace to those with a spouse, partner, or family member in the last stages of life.
- **Humor and Healing** (HaH) is a humor list for the online prostate cancer community.
- **Spirit** is a place to receive spiritual support for those dealing with prostate cancer.
- **WW** is for discussion and support for patients interested in Watchful Waiting.
- **Newly Diagnosed** is for those men with prostate cancer who are new to their diagnosis.

In closing, it is my hope you check out this great resource at www.ustoo.org/Events/ustoo_pp_page.htm to see what Nancy, Gary and other patients, families and health care professionals have to say. Please spread the word on this and the other resources of Us TOO.

Thank you, Tom

MEDICARE CHANGES

(Continued from page 1)

and access to cancer therapies.

These changes, according to a recent report by the Medicare Rights Center (MRC), has caused some physicians administering chemotherapy drugs to no longer furnish them. Instead, they request that patients purchase the drugs and bring them to the physicians' office. The MRC and other patient advocates say that this "brown-bagging" – having patients buying medications for administration – can be dangerous for several reasons:

- Many injected or infused drugs like those used to treat prostate cancer must be carefully handled or stored at certain temperatures. Physician offices are far more likely to know how to handle these medicines than patients, who may not understand the implications of improper handling on these delicate medications.
- Additionally, according to a recent court ruling, Medicare regulations specifically state that "where the patient purchased a drug and the physician administers it, the payment for the drug is denied by Medicare."

If your doctor requests that you "brown bag" your own medicines, please be aware of these concerns and make sure you have the information you need to get the best care – and ensure that your medications are covered.

Medicare officials need to hear from the prostate cancer community to ensure that the new payment system protects access and safe administration of appropriate therapies. Write to Dr. Mark McClellan, Centers for Medicare and Medicaid Services Administrator at 7500 Security Blvd., Mail Stop C5-11-24, Baltimore, MD 21244-1850 or send him an e-mail at mark.mcclellean@cms.hhs.gov.

LOCAL SALVAGE THERAPIES FOLLOWING RADIATION FAILURE FOR PROSTATE CANCER

Touma NJ, Izawa JI, Chin JL

J Urol, Vol. 173, pp. 373-9, 2005

PURPOSE: We reviewed the curative options available to patients with local failure after radical radiotherapy for prostate cancer and identified the patients best suited for such salvage therapies.

MATERIALS AND METHODS: A literature search of English language publications was done using the key terms salvage, prostatectomy, cryosurgery, brachytherapy and radiation failure.

RESULTS: Salvage radical prostatectomy offers 5-year biochemical relapse-free rates between 55 and 69%. Higher complication rates are reported with salvage compared to primary radical prostatectomy, including rectal injuries, bladder neck contracture and urinary incontinence. Cryosurgery biochemical response rates vary according to the definition of failure but they are generally lower than those of salvage radical prostatectomy. The local control rates of cryosurgery are acceptable. Major complications related to cryotherapy are urinary incontinence, impotence, pelvic pain and urinary retention. Experience with salvage brachytherapy has been limited but some success has been reported in terms of biochemical control.

CONCLUSIONS: Salvage prostatectomy for localized radiation failure is a good option in the patient with a life expectancy of at least 10 years, preradiation and preoperative prostate specific antigen less than 10 ng/ml, and localized preoperative stage with the understanding that complication risks are higher. Salvage cryotherapy is a valid option in patients with preoperative prostate specific antigen less than 10 ng/ml and Gleason score less than 8, clinical stage less than T3 who are hormonally naive. Salvage cryotherapy is especially suited for older patients with some comorbidities who are still considered to be at reasonable anesthetic risk. The study of brachytherapy remains in its infancy and the efficacy of this modality remains to be determined.

Reviewer's comments: Salvage local therapies for local failure of prostate cancer remain problematic for long-term disease control and complications that can adversely impact quality of life. Patient selection is key for a good outcome.

EFFECTS OF ANDROGEN SUPPRESSION AND RADIATION ON PROSTATE CANCER SUGGEST A ROLE FOR ANGIOGENESIS BLOCKADE

Woodward WA, Wachsberger P, Burd R, Dicker AP

Prostate Cancer Prostatic Dis
11 Jan 2005
[epub ahead of print]

Antiandrogen therapy is an important modality in the treatment of prostate cancer. Recent research into the role of angiogenesis in tumor growth and metastasis has uncovered links between antiandrogen therapy, radiation therapy and angiogenesis, which have exciting implications for the treatment of prostate cancer. Angiogenic cytokines such as vascular endothelial growth factor (VEGF) have been identified in prostate cancer cells and tumours, and androgens appear to stimulate VEGF. This article assesses the antiangiogenic effects of hormonal therapy and assesses the role that angiogenesis may play in the observed cooperation between hormonal and radiation therapies for prostate cancer.

doi:10.1038/sj.pcan.4500779

CANCER RATES DIFFER AMONG RACIAL AND ETHNIC GROUPS IN CALIFORNIA

Among Californians, black men face the highest risk of being diagnosed with cancer, and their rates are almost three times as high as those among South Asian groups, according to statistics from the California Cancer Registry and researchers at the Los Angeles Cancer Surveillance Program at USC/ Norris Comprehensive Cancer Center.

Cancer incidence and mortality rates differ so much among California ethnic groups that black men are actually five times more likely to die of cancer than are South Asian men, for example. Yet rates of certain cancers (such as liver and stomach cancer) are much higher among Koreans and Chinese than among blacks and other groups.

These findings are just a small part of the newly released report Cancer Incidence and Mortality in California: Trends by Race and Ethnicity 1988-2001, an examination of 14 years of statewide cancer data. The Los Angeles Cancer Surveillance Program, or CSP, produced the report with data from fellow regional cancer registries. About 140,000 cancer cases and 50,000 cancer deaths are reported statewide each year.

The report is the first statewide study of cancer incidence rates in ethnic communities that are seldom examined, such as South Asians (Asian Indian, Bangladeshi, Pakistani and Sri Lankan) and Vietnamese. It also highlights cancer in changing populations, such as Latinos. Such studies contribute to a better understanding of cancer.

By gender, the report shows that black men and non-Latino white women are hardest-hit, proportionately, by cancer. But cancer rates vary significantly by gender and ethnicity.

"Identifying differences and trends in cancer rates by race/ethnicity is the key to identifying how successful our cancer control efforts are, and tells us a lot about the causes of cancer, and how to prevent it," said Myles Cockburn, PhD, assistant professor of preventive medicine at the Keck School of Medicine of USC.

A sampling of the trends observed includes the following:

1. Prostate cancer was the most common cancer among men of all racial or ethnic groups except Koreans, for whom stomach cancer was most common, and Vietnamese, among whom lung cancer was most common.
2. Prostate cancer death rates were 10 times higher in blacks than in Asian groups.
3. Breast cancer was the most common women's cancer among all groups except Koreans, in whom lung cancer was most common.
4. Breast cancer incidence rates increased rapidly for all groups except Latinas, among whom incidence rates declined. In situ breast cancers increased rapidly among all groups, indicating far-reaching effects of mammography screening.
5. Cervical cancer rates declined among all racial and ethnic groups, likely due to screening.
6. Lung cancer death rates increased among women of all races and ethnicities.
7. Thyroid cancer rates increased steadily among most racial and ethnic groups.
8. Colorectal cancer rates, traditionally lower among Filipinos and Koreans, are increasing among these groups, as well as among other Asians.

Because California is home to a wide array of ethnic groups, both immigrant and native-born, and offers a unique opportunity to understand cancer among different communities. In the future, the diversity in ethnicity observed in California is very likely to be seen nationwide.

NewsRx.com, 30 December 2004

FDA INITIATES SEIZURE OF GINSENG BECAUSE OF POTENTIALLY RISKY PESTICIDE RESIDUES

At the request of the FDA, the U.S. District Court for the District of New Jersey issued a warrant for the seizure of imported ginseng held at FCC Products, located in Livingston, N.J.

The U.S. Marshals Service, accompanied by an FDA investigator, seized the ginseng. The exact amount and extent of distribution at this time is unknown, but an FDA spokeswoman estimated that roughly 200 kg of materials had been confiscated. Because of the uncertainty of the distribution, the FDA is issuing a nationwide warning to those who may have used this product.

The bulk and blended ginseng products held at FCC Products are adulterated under the Federal Food, Drug, and Cosmetic Act because they contain pesticide chemical residues that are unsafe. The pesticide chemical residues, procymidone and quintozene, are deemed unsafe because there has been no tolerance established for these residues in ginseng.

During an inspection of FCC Products, the FDA collected samples of the firm's ginseng, the bulk of which was found to contain the pesticide chemical residues procymidone and quintozene.

FCC Products refused to respond to requests for comment.

FDA News, 23 December 200

MORE PRECISE RADIATION THERAPY LETS PROSTATE CANCER PATIENTS AVOID ERECTILE DYSFUNCTION

Researchers at the University of Michigan Comprehensive Cancer Center are using innovative planning techniques to help men with prostate cancer avoid erectile dysfunction after radiation treatment.

By using MRI scans in addition to CT scans, radiation oncologists can identify the blood vessels that control erectile function and plan treatment to target the prostate more precisely, sparing those nearby vessels. Results from an initial study with 25 patients appear in the January issue of the International Journal of Radiation Oncology Biology Physics (Vol. 61, issue 1, pp 20-31).

Some 230,000 men were diagnosed with prostate cancer in 2004. While it's more common in older men, a growing number of men are being diagnosed in their 50s.

"As we treat younger men, erectile function is an important concern. We're often treating men in their 50s, and this is a very important issue for them. Most of the men I see are going to be cured. Once you start curing cancers at an extremely high rate, then the focus moves to quality of life," says Patrick W. McLaughlin, M.D., clinical professor of Radiation Oncology at the University of Michigan Medical School and director of Providence Hospital Radiation Oncology, with cancer centers in Southfield and Novi, both affiliated with the U-M Comprehensive Cancer Center.

Treatment for prostate cancer can involve surgery to remove the gland or radiation therapy. During surgery, the nerves that control erectile function may be severed - spawning new surgical techniques to avoid cutting those nerves.

But doctors are less sure what causes erectile dysfunction after radiation therapy. Erectile dysfunction among men without prostate cancer is most commonly caused by a problem in the blood vessels, and doctors do know that radiation causes obstruction of the vessels that fall within the treatment area. Using that as a starting point, the U-M team began investigating radiation-related erectile dysfunction as a blood vessel problem.

Typically, radiation oncologists rely on a CT scan to identify the prostate and plan treatment. But because of limitations in the CT scan, the images do not show the bottom of the prostate. Doctors instead estimate where the prostate ends, based on average distance from identifiable structures. The U-M study, using MRI in addition to CT scans to get a better picture of the whole prostate, found the distance between the prostate and the penile bulb ranged from 0.5 cm to 2.0 cm.

"We condemned one of the common tricks people try to use. By assuming an average distance of 1.5 cm between the prostate and the penile bulb, either you're going to treat way more than that or you're going to miss the prostate," McLaughlin says.

By taking the additional imaging, the U-M team was able to plan treatment to include the entire prostate but avoid the critical blood vessels below. Preliminary results suggest that avoiding the vessels prevents erectile dysfunction.

Because we can't see any detail of this area on CT scans, we just assume if we treat below the prostate it's no big deal. But it is a big deal. There is no cancer below the prostate, but there are critical structures related to erectile function as well as urine sphincter function. Treating below the prostate may result in needless problems," McLaughlin says. "I don't have much doubt from what I've seen that this approach is likely to have huge impact."

About one in two men who undergoes radiation therapy for prostate cancer is unable to have sex five years later unless Viagra or similar medications are used.

In addition, the vessels involved in erectile function also play a role in bowel and bladder control. The researchers suspect avoiding radiation to these areas will improve other quality of life issues, like urinary leakage and bowel problems.

NEWSWISE Medical News
6 January 2005

ABBOTT SEEKS FDA APPROVAL FOR PROSTATE CANCER DRUG

Abbott Laboratories Inc. said on Tuesday said it is seeking U.S. regulatory approval for a drug to treat advanced prostate cancer that has spread through the body.

The maker of drugs, nutritional products and diagnostic tests said its application was based on combined data from mid-stage and late-stage clinical trials of the drug, named Xinlay, which is intended for the treatment of metastatic hormone-refractory prostate cancer.

Previously named Atrasentan, Xinlay hit a major setback in February 2003 when Abbott disclosed data from a late-stage trial showing a non-statistically significant delay in progression of the disease.

In June 2004, researchers released data showing the treatment significantly delayed the progression of prostate cancer among patients in both mid-stage and late-stage clinical trials.

The oral drug blocks a protein known as endothelian receptor A, which plays a role in prostate cancer cell progression, particularly with regards to spread of disease to the bone.

Reuters, 14 December 2004

DIETARY FATS LINKED WITH PROSTATE CANCER AGGRESSIVENESS

Higher concentrations of prostatic polyunsaturated fatty acids (PUFA) correlate with a lower risk of invasive disease among men with early-stage prostate carcinoma, US investigators report in the December 15th issue of Cancer Volume 101, pp. 2744-54.

"What this research suggests is that there is a very plausible and probable link between the types of fat consumed after the cancer has already developed and the level of aggressiveness or the extent of disease at the time the cancer is diagnosed and treated," said lead author Dr. Vincent L. Freeman, of the University of Illinois at Chicago.

Studies of the effects of different types of dietary fat intake on prostate cancer risk and prognosis have had mixed results, Dr. Freeman and colleagues note. They point out that many in the field believe biological measures of dietary exposure will be more helpful in clarifying the relationship than studies using dietary recall.

To investigate the relationship between PUFA and invasiveness of early stage prostate carcinoma, Dr. Freeman's group tested 196 prostate tissue samples collected during radical prostatectomy for localized disease, using several measures of PUFA exposure. Fifty-two of the men had extracapsular extension, including 19 with seminal vesicle involvement.

The researchers found significantly lower levels of PUFA in the men with seminal vesicle involvement. Omega-3 fatty acid percentage and arachidonic acid percentage also were inversely related to the risk of seminal vesicle involvement, as was the ratio of omega 3 to omega 6.

There are a number of different mechanisms through which "good" fats like omega 3 fatty acids could help prevent cancer growth, Dr. Freeman noted. For example, while omega 6 acids such as linoleic acid can work through immune system pathways to fuel cancer spread and inhibit apoptosis, omega 3s can block these pathways from using "bad" fats as fuel. PUFAs can also influence communication both within and between cells in other ways, while oxidation of PUFAs can lead to DNA damage.

According to Dr. Freeman, the percentage of PUFAs in prostate tissue is likely an accurate marker for long-term fat consumption. "We are reasonably confident that that does reflect some longer term pattern of intake, a pattern of intake long enough to have influence over disease aggressiveness," he said.

The researchers conclude:

Because the differences in prostatic concentrations of PUFA were not large, levels associated with a reduced risk of locally advanced prostate carcinoma would appear to be achievable through dietary modification. However, the results of recent attempts to manipulate tissue nutrient levels through dietary modification have been mixed, suggesting that much technical work remains before this can become a feasible and effective preventive strategy."

Reuters Health, 5 January 2005

OSTEOPOROSIS PREVENTION NEGLECTED IN MEN TREATED FOR PROSTATE CANCER

Physicians generally do not take measures to prevent or treat osteoporosis in men with prostate cancer being treated with androgen deprivation therapy (ADT), even when other risk factors are involved, according to new research.

ADT is associated with accelerated rates of osteoporosis and fracture, Dr. Tawee Tanvetyanon, an oncologist at Loyola University Chicago Medical Center in Maywood, Illinois, notes in his paper, to be published in the January 15th issue of the journal Cancer.

To see whether physicians are properly addressing the increased risk, he retrospectively reviewed medical records of 184 patients who had received ADT with goserelin (Zoladex®) injections for 1 year or longer.

Dual energy X-ray absorptiometry scans had been ordered for 8.7% of subjects in the past 3 years. Similar numbers were receiving calcium and vitamin D supplements. Oral and intravenous bisphosphonate was given to 4.9% and 0.5%, respectively, over the previous year. None were receiving estrogen or calcitonin.

Concurrent risk factors, for example, smoking, alcohol dependency and comorbid illness - did not affect the likelihood that patients were being checked and treated for osteoporosis. "Theoretically, these patients have higher risks of osteoporotic fracture and should be deemed a priority," Dr. Tanvetyanon writes.

The only risk factor that independently predicted treatment for osteoporosis was the presence of bone metastases (hazard ratio 5.59).

"Primary care physicians provided the greatest number of interventions and cancer-related specialists provided the fewest," Dr. Tanvetyanon adds.

He suggests that guidelines for bone mineral density measurement and treatment interventions are necessary for patients undergoing ADT.

Reuters Health, 14 December 2004

'WATCHFUL WAITING' OK FOR SOME PROSTATE CANCERS

New research shows that it's possible to identify men with slowly progressive or latent prostate cancer, reflected by prostate specific antigen (PSA) levels that remain stable or fall over time.

These men are good candidates for a "watchful waiting" approach to managing their cancer, study investigators suggest. In other words, such patients can be monitored regularly and only treated if their cancer progresses.

"Watchful waiting remains a controversial prostate cancer treatment strategy," Dr. Stijn H. De Vries from Erasmus Medical Center in Rotterdam, the Netherlands, acknowledge in the December issue of the Journal of Urology.

They evaluated tumor characteristics at diagnosis and changes in PSA with time in 191 men with prostate cancer detected via screening. All the men were initially managed with watchful waiting based on the advice of their doctor or their own preference.

Of the 191 men, 161 had "favorable" tumor characteristics and a PSA less than 10.

During an average follow-up of 40 months, PSA levels declined for 35 men. In 85 men with increasing PSA levels, the average PSA doubling time -- a measure of tumor activity -- was nearly 10 years.

During follow-up, a total of 30 men underwent treatment including radiation therapy and surgical removal of the prostate. For 25 of these men, signs of cancer progression triggered a recommendation for treatment, but five men decided to go ahead even though their cancer appeared stable.

Six men died during follow-up, none of prostate cancer.

Reuters Health, 28 December 2004

PRELIMINARY ASSESSMENT OF MAGNETIC RESONANCE SPECTROSCOPIC IMAGING IN PREDICTING TREATMENT OUTCOME IN PROSTATE CANCER PATIENTS AT HIGH RISK FOR RELAPSE

Pucar D, Koutcher J, Shah A, et al

Clin Prostate Cancer
Vol. 3, pp. 174-81, 2004

The purpose of the study was to determine whether 3D proton magnetic resonance spectroscopic imaging (MRSI) can predict treatment outcome in high risk patients with prostate cancer. Endorectal magnetic resonance imaging (MRI) and 1H-MRSI were performed in 16 patients with prostate cancer who were considered high risk because of clinical stage T3-4, Gleason score $\geq$ 8, and/or prostate-specific antigen (PSA) level > 20 ng/mL. Patients were treated with chemotherapy/hormone therapy, underwent radical prostatectomy (RP) or radiation therapy, and were followed for PSA relapse (follow-up, 19-43 months). The ratio of choline plus creatine to citrate was used to localize peripheral zone cancer. An MRSI risk score on a scale of 0-3 was derived from the volume and degree of metabolic abnormality. Magnetic resonance spectroscopic imaging risk score, MRI tumor/node (TN) stage, clinical stage, Gleason score, and PSA were used as predictors of pathologic stage in patients treated with RP (n = 10) and PSA relapse in all patients. Magnetic resonance imaging TN stage ($P < 0.01$) and MRSI risk score ($P < 0.05$) correlated with pathologic stage, but clinical stage did not ($P = 0.35$). Magnetic resonance imaging TN stage was the only significant predictor of PSA relapse in the univariate analysis ($P < 0.05$). Although the MRSI risk score did not reach significance ($P = 0.13$), 6 patients with a score < 0.9 were relapse-free, whereas 7 of 10 patients with a score > 0.9 relapsed. Magnetic resonance imaging and MRSI risk assessments agreed in 15 of 16 patients. These preliminary results suggest that tumor metabolic assessment may indicate treatment outcome in high-risk patients with prostate cancer. Although MRSI did not provide added prognostic value to MRI in this small number of patients, MRSI might increase the confidence of the clinician in assessing risk on MRI by contributing supporting metabolic data.

Reviewer's comments: This preliminary report highlights the inherent limitations of nuclear scans in their sensitivity to detect cancer. Biochemical markers having the sensitivity to detect microscopic disease activity after treatment will likely prove to be better indicators of successful treatment outcome.

INNOVATIVE 'IMMUNOCAPTURE' TECHNOLOGY COMBINED WITH NUCLEIC ACID TESTING (NAT) MAY HELP DETERMINE AGGRESSIVENESS OF MALIGNANCIES AND AID IN PATIENT MONITORING

Gen-Probe (Nasdaq: GPRO - News) has licensed technology from AdnaGen, a private company based in Germany, that may help increase the accuracy of molecular diagnostic tests to detect prostate and other cancers, help determine the aggressiveness of these malignancies, and monitor responses to therapy.

AdnaGen's proprietary technology enables detection of rare, circulating tumor cells that are an early event in cancer metastasis. This is accomplished through two steps that combine the benefits of immunoassay and nucleic acid testing. This combination of technologies

GEN-PROBE

(Continued from page 7)

increases both the sensitivity and specificity of cancer cell detection in body fluids such as blood and urine.

"We believe our PCA3 prostate cancer test could be a breakthrough based solely on our current technology platform, but incorporating AdnaGen's innovative technology into a combination product could yield markedly improved sensitivity and specificity, said Henry L. Nordhoff, chairman, president and chief executive officer of Gen-Probe. as well as greater prognostic value. We also expect to apply AdnaGen's technology to future assays for other cancers."

Prostate cancer is one of the most challenging cancers to treat because the aggressiveness of tumors can be difficult to determine. As a result, new diagnostic tools are needed that enhance understanding of this cancer, and potentially improve the types and timing of medical intervention.

Under the terms of the agreement, Gen-Probe will gain exclusive access to AdnaGen technology for molecular diagnostic tests for prostate and bladder cancers. Gen-Probe will pay AdnaGen license fees of $1 million within 30 days of signing, and $750,000 in the first quarter of 2006 or upon patent issuance, whichever comes later. Gen-Probe also may pay AdnaGen three milestones totaling an additional $2.25 million based on certain regulatory and commercial events. In addition, Gen-Probe will pay AdnaGen royalties on sales of any products developed using AdnaGen's technology.

"By combining AdnaGen's technological advancement in tumor diagnostics with Gen-Probe's impressive track record of successfully taking innovative products to the market, we believe that the cooperation between AdnaGen and Gen-Probe is very likely to become a success," commented Winfried H. Albert, chief operating officer and chief scientific officer of AdnaGen. "The joined expertise will facilitate a speedy adaptation of AdnaGen's technology onto Gen-Probe's technology platform as well as a timely introduction of the novel tumor diagnostics."

PRNewswire-FirstCall
3 January 2005

ESTROGEN-LIKE COMPONENT OF PLASTIC STIMULATES GROWTH OF CERTAIN PROSTATE CANCER CELLS

An estrogen-like chemical commonly used to manufacture plastic food containers has been shown to encourage the growth of a specific category of prostate cancer cell, potentially affecting the treatment efficacy for a subset of prostate cancers.

According to a study published in the January 1 issue of ***Cancer Research***, such prostate cancer cells proved to be vulnerable to exposure to the chemical BPA (bisophenol A), an industrial chemical and non-steroidal environmental estrogen used in the manufacture of food cans, milk container linings, food storage containers and water supply pipes. About 2.5 billion pounds of the chemical are produced each year.

Reference:

Wetherill YB, Fisher NL, Staubach A, et al. Xenoestrogen action in prostate cancer: Pleiotropic effects dependent on androgen receptor status. Cancer Res Vol. 65, pp. 54-65, 2005.

AACR website, 12 January 2005

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