

THE DIGITAL EXAMINER



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www.pccncalgary.org

Talk to someone who has been there

BREAKING NEWS!

Jevtana® (cabazitaxel) injection approved by U.S. FDA after priority review. First and only therapy to provide significant survival benefit in second-line metastatic hormone-refractory prostate cancer.

Sanofi-aventis announced today that the U.S. Food and Drug Administration (FDA) has granted marketing authorization for Jevtana® (cabazitaxel) Injection in combination with prednisone for the treatment of patients with metastatic hormone-refractory prostate cancer (mHRPC) previously treated with a docetaxel-containing treatment regimen.

Jevtana, a microtubule inhibitor, in combination with prednisone was approved based on results from the Phase 3 TROPIC clinical study involving 755 patients with mHRPC previously treated with a docetaxel-containing treatment regimen. Results from this trial demonstrated a statistically significant 30% [HR=0.70 (95% CI: 0.59-0.83); P<0.0001] reduction in risk of death from mHRPC among patients taking Jevtana in combination with prednisone compared with an active chemotherapy regimen consisting of a standard dose of mitoxantrone and prednisone. Investigator-assessed tumor response rates using Response Evaluation Criteria in Solid Tumors (RECIST) were 14.4% and 4.4% for cabazitaxel-treated and mitoxantrone-treated patients respectively, p=0.0005. No complete responses were observed on either arm.

"This is truly a significant announcement for the prostate cancer community, addressing an unmet medical need. With the approval of Jevtana, health care professionals now have a new treatment option for patients with the most advanced stage of prostate cancer and for whom there have been few options," said Oliver Sartor, M.D., TROPIC North American principal investigator, Piltz Professor for Cancer Research at Tulane Medical School, New Orleans. "Jevtana in combination with prednisone is the only FDA approved regimen to significantly improve overall survival in patients previously treated with docetaxel-based chemotherapy regimen."

In the TROPIC Study, the most common (greater than or equal to 10%) adverse reactions (grade 1-4) were neutropenia, anemia, leukopenia, thrombocytopenia, diarrhea, fatigue, nausea, vomiting, constipation, asthenia, abdominal pain, hematuria, back pain, anorexia, peripheral neuropathy, pyrexia, dyspnea, dysgeusia, cough, arthralgia, and alopecia. The most common (greater than or equal to 5%) grade 3-4 adverse reactions in patients who received Jevtana were neutropenia, leukopenia, anemia, febrile neutropenia, diarrhea, fatigue, and asthenia.

The rolling new drug application (NDA) submission was completed in March 2010 and was granted priority review in April 2010; Jevtana was approved by the FDA less than three months later. Jevtana is expected to be available as a marketed product in the United States this summer. A registration dossier of Jevtana is also under regulatory review by other regulatory authorities, including the European Medicines Agency. For more information please see www.urotoday.com or www.prostatecancerblog.org/?p=286

PCCN Calgary's
next
monthly meeting will be held
at

7:30 PM on
Tuesday

July 13, 2010 in
the Foothills
auditorium in
the Foothills

Hospital.

We will be

featuring a
video from the
PCRI confer-
ence held in Los
Angeles in 2009.

Come join us for
learning and
discussion.

Women and Prostate
Cancer (WAPC) and
Men's Peer Group
meetings take a
summer hiatus and
will resume in

September. Please
stay tuned.

If you have a
concern of an urgent
nature please

Contact Karen at
403.455.1916

New Tests for Prostate Cancer

Two new tests promise to cut down on the number of biopsies now taken from men suspected of having prostate cancer, researchers report.

The tests -- still in the early stages of development -- might also offer better clues about which cancers require immediate treatment and which can be left for so-called "watchful waiting," researchers reported Tuesday at the American Urological Association's annual meeting, in San Francisco.

Both tests check for increased levels of genetic material -- one for the DNA of which genes are made, the other for the RNA that carries the messages from those genes. And both tests appear to add certainty to the suspicion of prostate cancer provided by the most widely used test for prostate cancer, the prostate-specific antigen (PSA) blood screen.

The test Dr. Rakesh Singal, an associate professor of medicine at the University of Miami Miller School of Medicine, described looks at blood levels of specific DNA. Prostate cancer can increase those levels, because malignant cells grow abnormally fast and cause the death of other cells, Singal explained.

The study included 252 men referred for prostate biopsies because of abnormal PSA test readings. Singal's team found that high levels of the target DNA were significantly associated with the presence of a cancer.

"What we think will probably happen in the future is that those men who have high PSA levels will [also] have this test," Singal said. "If the DNA levels are high they will have biopsies; if low, they can be observed periodically."

The other test, described by Dr. E. David Crawford, a professor of urology at the University of Colorado, is targeted to elevated levels of PCA3 "messenger RNA" in urine. Again, elevated levels of this genetic material are associated with the presence of a tumor.

In the study, nearly 2,000 men with elevated PSA levels or abnormal results on a digital rectal examination (which measures prostate enlargement) also underwent PCA3 urine tests, followed by biopsies.

The PCA3 readings were significantly higher in those men whose biopsies turned out positive for cancer, the team found. In addition, "PCA3 level reflects the aggressiveness of cancer," Crawford said, so that the test could be used to single out prostate cancers requiring immediate surgery or radiation treatment.

Further studies are needed to determine whether PCA3 testing could serve that purpose, he said. In the meantime, the immediate effect of the new data is to help develop "a new paradigm" for early detection of cancer, in which PCA3 testing would go along with PSA testing and digital rectal examinations, Crawford said.

That combination could reduce the need for biopsies, which are both expensive, cause discomfort and are associated with a risk of infection, he said.

<http://health.usnews.com/health-news/family-health/cancer/articles/2010/06/02/new-tests-for-prostate-cancer-might-bring-more-certainty.html>

Acupuncture for hot flashes in patients with prostate cancer

Division of Hematology and Medical Oncology, Oregon Health and Science University, Portland, Oregon.

To determine the effect of acupuncture on hot flash frequency and intensity, quality of life, and sleep quality in patients undergoing hormonal therapy for prostate cancer. Hot flashes are a common adverse effect of hormonal therapy for prostate cancer.

Men who had a hot flash score >4 who were receiving androgen deprivation therapy for prostate cancer underwent acupuncture with electrostimulation biweekly for 4 weeks, then weekly for 6 weeks, using a predefined treatment plan.

The primary endpoint was a 50% reduction in the hot flash score after 4 weeks of therapy, calculated from the patients' daily hot flash diaries. The hot flash-related quality of life and sleep quality and biomarkers potentially related to hot flashes, including serotonin, calcitonin gene-related peptide, and urinary 5-hydroxyindoleacetic acid, were examined.

A total of 25 men were enrolled from September 2003 to April 2007. Of these, 22 were eligible and evaluable. After 4 weeks, 9 (41%, 95% confidence interval 21%-64%) of 22 patients had had a >50% reduction in the hot flash score. Of the 22 patients, 12 (55%, 95% confidence interval 32%-76%) met this response definition at any point during the therapy course. No patient had a significant increase in hot flash score during therapy. A reduced hot flash score was associated with improvement in the hot flash-related quality of life and sleep quality.

Multiple placebo-controlled trials have demonstrated a 25% response rate to placebo treatment for hot flashes. Of the 22 patients, 41% had responded by week 4 and 55% overall in the present pilot study, providing evidence of a potentially meaningful benefit. Additional studies of acupuncture for hot flashes in this population are warranted.

Written by: Beer TM, Benavides M, Emmons SL, Hayes M, Liu G, Garzotto M, Donovan D, Katovic N, Reeder C, Eilers K.
Reference: Urology. 2010 May 20. Epub ahead of print.



Can dogs sniff out Prostate Cancer?

New research suggests that dogs can sniff out signs of prostate cancer in human urine, adding to the ongoing debate over the disease-detecting powers of man's best friend.

Some scientists have questioned similar reports of dogs with such diagnostic powers in recent years, but the lead author of this latest study said the findings are promising and could lead to better cancer-sensing technology. "The dogs are certainly recognizing the odour of a molecule that is produced by cancer cells," said French researcher Jean-Nicolas Cornu, who works at Hospital Tenon in Paris. The problem, he said, is that "we do not know what this molecule is, and the dog cannot tell us." Still, the report could represent a significant development since cancer often goes undetected until it is too late to treat.

Urine tests can turn up signs of prostate cancer, Cornu said, but miss some cases. Some types of molecules give a distinct odour to urine, "but today there is no means to screen odours from urine and separate them," he said, and no way to link them to cancer.

Enter the dog, whose powers of smell are far greater than those of humans. For this study, two researchers spent a year training a Belgian Malinois shepherd, a breed already used to detect drugs and bombs.

The dog was trained to differentiate between urine samples from men with prostate cancer and men without. Ultimately, researchers placed groups of five urine samples in front of the dog to see if it could identify the sole sample from a man with prostate cancer.

The dog correctly classified 63 out of 66 specimens.

If the findings hold up in other studies, they'll be "pretty impressive," said urologist Dr. Anthony Y. Smith, who was to moderate a discussion on the findings Tuesday at the American Urological Association annual meeting in San Francisco.

Skeptical researchers are concerned about factors that could throw off the results, said Smith, chief of urology at the University of New Mexico. Among other things, scientists wonder if the animals used in such studies pick up on subconscious signals from researchers.

Still, in this study, it's hard to imagine anything "other than the dogs somehow being able to smell something that we don't smell," Smith said.

If these findings are valid, they could lead to the development of more accurate tests that don't require unnecessary biopsies, Smith said.

The next steps are to determine precisely what the dogs are sniffing and to develop an "electronic nose" to detect it, Cornu said. Other dogs are already being trained, he said.

Could doctors and hospitals employ dogs and researchers to detect prostate cancer? Cornu said that's possible, but it could cost as much as hiring two full-time scientists. www.health.usnews.com/health-news/family-health/cancer/articles/2010/06/01/dog-sniffs-out-prostate-cancer-in-small-study.html

THRIVE CENTRE

Individualized Fitness Testing for Cancer Survivors

An innovative facility at the University of Calgary aiming to empower and improve the quality of life of participants, through individualized and specific exercise assessment and program design. All assessments and program design performed by Certified Exercise Physiologists and trainers with cancer and exercise research expertise.

TESTING PACKAGES

Cardio Thrive Package: \$150 includes 1.5hr assessment & 1.0hr session with trainer on different day

Aerobic exercise is essential to the health of our cardiovascular system, and particularly important in the recovery from cancer treatments which may have had detrimental effects on the heart and lungs. If you are ready to start the process of reclaiming your cardiovascular fitness, we can help you get started safely and effectively. Exercise intensity is an extremely important variable in the success of any training program, and especially in the case of cancer survivors wanting to optimize the benefits of exercise while minimizing fatigue.

This package provides participants with an individualized, research-based aerobic training program, using direct blood lactate measurement to determine optimal workout intensities. After completing our comprehensive aerobic assessment, you will receive a specific 3x/week aerobic program that will ensure you are training effectively. The program will be put into action during your subsequent session with a certified trainer, ensuring you understand how to implement all components of your program.

Functional Thrive Package: \$150 includes 1.5hr assessment & 1.0hr session with trainer on different day. Muscular strength, endurance, flexibility and balance are key components of functional fitness. Together, they determine your ability to perform daily activities, enjoy recreational pursuits, cope with emergencies, reduce injury, and maintain functional independence with age.

This package is tailored to each individual participant, and may include range of motion and postural assessments to detect any muscles imbalances or limitations following surgery and treatment. Various strength, endurance, flexibility and girth measurements will be made to assess function, to compare to normative data, to identify and monitor for lymphedema, and to develop your personalized muscular fitness program. During a subsequent session, a certified trainer will guide you through the prescribed exercises, each selected to correct imbalances and help you to achieve your highest level of physical functioning.

Extra Workout Sessions: \$40 includes 1.0hr with trainer. Only available for those who have completed the Cardio or Functional Thrive Assessment Package(s). Our certified trainers can be available for extra sessions to work with you in the University of Calgary Fitness Centre. This is an ideal option if you find you need a little more time with your trainer to get acquainted with your new program, wish to have additional follow-ups, or like the motivation and accountability a trainer can provide. To book a session call 403.210.6983.



PCCN Calgary Warriors

The Warriors are a caring and compassionate group, well organized and full of information for those men and their families dealing with advanced prostate cancer. The Warriors serve the very important needs of hormone refractory PCCN Calgary members and all those who have an interest in management of advanced prostate cancer. The Warriors meet on the second Tuesday of each month at 6:14 pm prior to the main PCCN Calgary meeting. Warriors meet just outside the auditorium at Foothills Hospital in room #AGW2. Signs will be posted. Men with advanced prostate cancer, their partners and family members are most welcome to attend! For more information call Fred McHenry at 403.282.3920

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Women and Prostate Cancer
Women and Prostate Cancer (WAPC) and Men's Peer Group meetings will take a summer hiatus and will resume in September. Please stay tuned.

If you have questions please call Karen at 403-455-1916
Women Against Prostate Cancer is also a good resource.
www.womenagainstoprostatecancer.org

Many thanks to our many friends and supporters!

PCCN Calgary has many generous individuals and companies who support our community work. We do not get government funding. On behalf of our 900+ members, thank you for your generosity. With your support we will continue our good work in 2010, our fifteenth year, and onward!

Newsletter * General Meetings * One-On-One visits * Speakers * Website

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Please make cheques payable to
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or donate online through www.canadhelps.org**