MDV3100 in Prostate Cancer ‘Exceeded Expectations’

Results from a large phase 3 study of the investigational agent MDV3100 in advanced prostate cancer “exceeded our expectations,” said principal investigator Howard Scher, MD, chief of the genitourinary oncology service at the Memorial Sloan-Kettering Cancer Center in NY. The phase 3 study, known as AFFIRM (NCT00974311), was conducted in men with metastatic castration-resistant prostate cancer (CRPC) who had progressed after treatment with docetaxel-based chemotherapy. The trial was stopped in November 2011 after a planned interim analysis showed a 37% reduction in the risk for death with MDV3100 over placebo (median, 18.4 vs. 13.6 months; hazard ratio [HR], 0.631; P < .0001).

More results from this trial were released ahead of their presentation at the 2012 Genitourinary Cancers Symposium in San Francisco, CA, at a presscast organized by the American Society of Clinical Oncology (ASCO), one of the sponsors of the meeting.

“Wow! Very impressive!” said Nicholas Vogelzang, MD, from US Oncology Research, who moderated the presscast. “The 18.4-month median survival is unprecedented,” he said.

The results from AFFIRM are part of the approval application that the manufacturer, Medivation, has already filed with the manufacturer, Medivation, has already filed.

(Continued on page 8)

Prostate Cancer Bone Mets Target of New Agent

Radium chloride (Alpharadin®) halved risk of pathologic bone fracture and spinal cord compression and reduced the need for external beam radiation (EBRT) by a third in castrate-resistant prostate cancer (CRPC) metastatic to bone, A. Oliver Sartor, MD, of Tulane University in New Orleans, LA and colleagues found. The injectable drug also significantly boosted overall survival by 30% to 14.0 months versus 11.2 months with placebo in the trial. Results in the ALSYMPCA (Alpharadin in Symptomatic Prostate Cancer) trial were reported at a press briefing in advance of presentation at the 2012 ASCO-AUA-SUO Genitourinary Cancers Symposium in San Francisco, CA.

“We believe this novel alpha-pharmaceutical – the very first one to be tested in all of medicine – may provide a new standard of care for the treatment of patients with bone metastases in advanced prostate cancer,” Sartor told reporters. Radium is a first-in-class agent that acts like calcium and localizes to areas of bone stroma damaged by tumor, where the short-range alpha particle radiation reaches only adjacent cells without hurting normal tissue.

ALSYMPCA included 922 men with confirmed symptomatic CRPC and at least two bony metastases, but no vis-

(Continued on page 5)

Benefits of Amgen’s Xgeva Don’t Outweigh Risks

An FDA panel on Wednesday voted 12-1 that the benefits of Amgen’s Xgeva (denosumab) did not outweigh its risks in patients with castrate-resistant prostate cancer (CRPC). “The effect of the studied compound is quite weak with no effect on survival or the overall course of the disease in general,” commented panelist Ronald Richardson.

In staff documents released ahead of the meeting, agency staff said that while the drug appeared to reduce the risk of developing bone metastases in a late-stage study involving patients with CRPC, it did not increase overall survival and carries significant side effects.

At the meeting, panelists termed evidence that patients taking Xgeva experienced a four-month delay in the spread of cancer to the bones as a “statistical benefit,” but not one that resulted in increased survival or higher quality of life for patients. Panel chair Wyndham Wilson remarked that “if it was one year we probably wouldn’t even be here today, no one is denying that, but the magnitude here is quite low.”

Panel members also expressed concern about the drug’s safety profile, including osteonecrosis of the jaw in about 5 percent of the 1432 patients studied. In addition, staff questioned whether the drug may “shift the pattern of metastases to

(Continued on page 8)
MEDICARE WILL KEEP COVERING PROSTATE CANCER SCREENING

After Congressmen Dennis Kucinich (D-OH), Dan Burton (R-IN) and Don Young (R-AK) organized a bipartisan group of 44 Members of Congress to object to a recommendation by the United States Preventative Task Force (USPTF) that healthy men should not receive a blood test to screen for prostate cancer, Health and Human Services Secretary Kathleen Sebelius agreed to overrule the recommendation.

“This victory preserves the right of doctors to decide, with their patients, whether a PSA test can be used as another indicator of a man’s health. It is good for the doctor, the patient and families,” said Kucinich. If accepted, the USPTF recommendation would have eliminated coverage for the blood test for tens of thousands of men over the age of 50 who rely on Medicare coverage.

“One in six men will be diagnosed with the disease during their lifetimes and 30,000 American men still die from it annually. There is substantial evidence which shows that screening helps catch the presence of prostate cancer early,” said Kucinich. The disease is especially deadly for three groups: African American men, those with a family history of the disease and men over age 65. The prostate specific antigen test, called PSA, is one of two commonly-used methods to screen for it, and early-stage treatment is considered the most effective tool in fighting it.


FINASTERIDE COMBO BRINGS DOWN PSA AFTER BIOCHEMICAL RECURRENCE (BCR)

Finasteride and flutamide in combination produce significant declines in PSA in men with BCR after local therapy, researchers report. Dr. Paul J. Monk of Arthur G. James Cancer Hospital and Richard J. Solove Research Institute in Columbus, OH and colleagues note that about a third of men treated for localized prostate cancer will have serological progression.

As an alternative to androgen deprivation therapy (ADT) – which has a high response rate but a myriad of side effects – the researchers propose peripheral androgen blockade with a 5-alpha reductase inhibitor (finasteride) and an antiandrogen (flutamide).

“Because patients with PSA-only recurrences after definitive local therapy are not necessarily destined to die of their disease, they are excellent candidates for therapy that may have lower toxicity, while retaining the potential to control their disease,” the investigators said in their report, published online in the journal Cancer on 16 December 2011. They tested the effect of daily therapy with finasteride 5 mg and flutamide 750 mg in 99 men who’d each had a PSA increase of at least 1 ng/mL. The PSA level fell by at least 80% in 96% of subjects, and it became undetectable (<0.2 ng/mL) in 73%. The median time to a nadir value was 3.2 months.

The median time to PSA progression was 85 months. The five-year overall survival rate was 87%, and with a median follow-up of 10 years, the median survival time has not been reached. Currently 22 patients remain on therapy. Of the 77 patients off protocol treatment, 43 have died, including 13 who died of progressive prostate cancer.

Eighteen men stopped therapy for side effects, mainly diarrhea, liver enzyme elevations, and breast enlargement. Another 21 experienced disease progression. Nine withdrew their consent.

“The combination of finasteride and flutamide was well tolerated, durable and active making it a good option to incorporate in a controlled study in this important population of men,” Dr. Monk said.”

Reuters Health, 12 January 2012
Ask Doctor Snuffy Myers

Editors’ note: This column contains opinions and thoughts of its author and are not necessarily those of Us TOO International.

Q: I am wondering if you can shed some light on the probability of my having metastasis-free survival. In January 2003, my PSA was 2.9 ng/mL but rose to 4.2 in June. This quick PSA rise alarmed me, and in July I began a mostly pescatarian diet. In September when my PSA was 3.0 ng/mL, I underwent a prostate biopsy which only revealed PIN. A second biopsy in December was positive for prostate cancer in one of 12 cores. I had an RP in April 2004 and was found to have organ-confined 3+3=6 disease in both halves of the gland classified as T1a sic (T2a). My PSA readings after RP remained < 0.1 ng/mL until November 2009, when I experienced PSA rise to 0.2 ng/mL. So far, this has been an isolated occurrence and my last PSA done in November 2011 was < 0.1 ng/mL.

I wonder about the significance of that isolated biochemical recurrence. Do you think I have a number of PCa stem cells lurking just below the detection level of 0.2 ng/mL, or is it possible that the stem cells making up the 0.2 reading in November 2009 have since been starved to death by the pescatarian, heart-healthy diet I have been following? How reproducible and accurate are PSA assays?

A: Your case is very interesting. First, a single PSA of 0.2 ng/mL is not sufficient for me to diagnose recurrent prostate cancer. Laboratory variation for an ultrasensitive PSA assay is normally below 10% for PSA values in this range,

(Continued on page 6)

Us TOO Wants to Answer Your Questions!

Dr. Myers would love to provide direct answers to questions posed by Us TOO members. Instead of printing questions answered in the Prostate Forum, we’d rather provide readers who subscribe to both publications with fresh content.

Questions about imaging, active surveillance, and biochemical relapse would be particularly appreciated right now.

Send questions to Jackie@ustoo.org or call the Helpline at 800-808-7866.

Oncologic therapies often cause long-term toxic effects, with resulting morbidity and costs. A new study has shown that prostate cancer treatment with external-beam radiation therapy (EBRT) resulted in more long-term toxicities and treatment-related costs than radical prostatectomy (RP) and brachytherapy (BT).

EBRT was the most expensive of the 3 treatments, whereas BT had the lowest cost per patient-year and the lowest percentage of treatment-related toxic effects.

“The long-term toxicity and cost per patient-year of the major prostate cancer treatment modalities differ,” said lead author Jay Ciezki, MD, from the Department of Radiation Oncology at the Cleveland Clinic, OH, who presented the highlights of the study at a presscast in advance of the 2012 Genitourinary Cancers Symposium held in San Francisco, CA. “EBRT is the most toxic and most costly.”

The authors note that treatment-related toxicity in prostate cancer is rarely reported more than 5 years after therapy. In this study, Dr. Ciezki and colleagues used the Surveillance, Epidemiology, and End Results (SEER)–Medicare database to access 16 years of follow-up data on toxic effects that required procedural intervention.

“We identified procedural billing codes associated with toxicity-related treatments,” explained Dr. Ciezki. We then “obtained information on the Medicare reimbursement rates for the initial treatment and any toxicity-related interventions.” With this information, they computed the cost per patient-year for each treatment over time.

From 1991 to 2007, a total of 137,427 men 65 years or older at the time of their prostate cancer diagnosis, for whom prostate cancer was their only cancer diagnosis, were identified in the SEER–Medicare database. Of this group, 59,559 (43.3%) were treated with RP, 60,806 (44.2%) were treated with EBRT, and 17,062 (12.4%) treated with BT. None of the patients in this cohort received combined therapy. The median follow-up for the entire series was 71 months.

Overall, 10,585 (7.3%) patients experienced a toxic effect that required some type of intervention. Treatment with EBRT resulted in the most treatment-related toxicities, followed by RP and then BT (8.8% vs. 6.9% vs. 3.7%). Overall, 7.1% of patients treated with EBRT experienced genitourinary (GU) toxic effects, such as urethral strictures and bladder bleeding, as did 6.7% of those treated with RP and 3.4% of those treated with BT.

Gastrointestinal (GI) events were also more common with EBRT than with RP or BT (1.7% vs. 0.1% vs. 0.3%). Of the GI adverse events, the most common was rectal bleeding; cauterization of rectal bleeding was reported in 0.8% of all patients. Of the GU adverse events, dilation of a urethral stricture was the most common intervention, reported in 3.6% of all patients.

Cost also differed among the 3 therapies. BT had the lowest cost per patient-year, at $2,557.36. This was followed by RP, which was slightly more expensive at $3,205.71, and EBRT, which cost the most at $6,412.29.

According to Nicholas J. Vogelzang, MD, from US Oncology Research, who moderated the presscast, “this is a fascinating work.” He added that it begs the question: Why BT is the least used, considering that it is effective but less toxic and costly than the other treatments?

“The lower cost is impressive,” he said, “I’m surprised we don’t see more of this modality.”

Dr. Ciezki pointed out that BT might have gotten off to a slow start because, when the technique was introduced in the 1990s, it was targeted at low-risk patients.

Medscape Medical News, 1 February 2012

Want to learn more about local prostate cancer support group activities? Read the Chapter News! at www.ustoo.org!
In mid-January, Congressmen Joe Baca (D-CA) and Jon Runyan (R-NJ) sent a letter to the Secretary of the Department of Health and Human Services (HHS), Kathleen Sebelius, regarding the United States Preventative Services Task Force’s (USPSTF) recent draft recommendations on the use of the PSA test. The PSA test is a preventative measure used to detect prostate cancer in men above the age of 50.

The draft recommendation from the USPSTF stated that the PSA test should be downgraded to a “D” rating, which means “there is moderate or high certainty that the service (PSA test) has no net benefit or that the harms outweigh the benefits.” This classification could result in a large number of men declining the test, despite the fact that early detection of the cancer dramatically increases a man’s chance of survival.

“The PSA test is responsible for saving the lives of thousands of men across the United States,” said Rep. Baca. “It would be a terrible mistake for HHS to disregard this vital preventive service without first doing its due diligence to ensure the health and safety of American men is not jeopardized. I thank Rep. Runyan for his bipartisan work on this issue. Moving forward, the Prostate Cancer Task Force will continue our efforts to ensure men have the education and awareness necessary for early detection of prostate cancer.”

“I have very strong concerns about the USPSTF’s suggestion that the PSA test is no longer as beneficial as previously reported,” said Rep. Runyan. “Thousands upon thousands of men have relied on this test for early detection of prostate cancer. This change could result in a dramatic shift in how our nation tests and treats prostate cancer and I am eagerly waiting for the Secretary’s response. I would like to thank Congressman Baca for his dedication to this cause. He has been a great ally in the fight against prostate cancer.”

“If the USPSTF recommendation goes forward, all men could lose access to early screening, even men at greatest risk of developing prostate cancer – African American men, men with a family history, and Vietnam Veterans exposed to Agent Orange,” said Scott Williams, Vice President of Men’s Health Network. "We call on Members of Congress to join Representatives Runyan and Baca’s call for a reexamination of the draft recommendation.”

Prostate cancer is not just a disease that affects men, the wives and children of these cancer patients are also affected. The proposed change could end a method to early detection of this cancer.

www.runyan.house.gov, 18 January 2012
ceral metastases. Most participants had progressed after docetaxel (Taxotere®), but some had been deemed unfit for docetaxel, which Sartor noted is a group often excluded from trials. Both the 223radium and placebo groups got best standard of care, which could include second hormonal therapies but not chemotherapy, experimental therapy, or some kinds of RT.

The intervention extended time to first skeletal-related event (SRE) to 13.6 months vs. 8.4 on placebo, which was a 39% relative improvement (P=0.00046). Results for the skeletal-related component endpoints showing an advantage for 233radium vs. placebo were:

1. A 55% relative reduction (RR) in pathologic bone fracture (3.6% vs. 6.7%, P=0.013)
2. A 56% RR in spinal cord compression (3.1% vs. 6.0%, P=0.016)
3. A 35% RR in EBRT (22.6% vs. 26.9%, P=0.0038)

Surgical intervention for SREs was 20% less common with 223radium, but this difference was not statistically significant (P=0.69). “This finding on spinal cord compression is very clinically significant,” Sartor said, pointing to the possibility of paralysis. The safety profile, too, looked good. Grade 3 or 4 events were essentially no different than with placebo, including anemia and other hematologic events, he noted.

Press conference moderator Nicholas J. Vogelzang, MD, medical director of the Developmental Therapeutics Committee of US Oncology and an investigator in the trial, echoed the excitement voiced over the primary survival results.

“The data speak for themselves,” he said, anticipating a big impact in clinical practice. “In a simple, additive way, we would expect the survivals to be fairly dramatically pushed forward.” Beyond additive benefits from sequential therapy, combinations might be synergistic, Sartor suggested.

The FDA agreed to fast-track review of 223radium, and that submission is under way based on the ALSYMPCA results without a need for additional data anticipated, according to Sartor.

**ALPHARADIN RESULTS**
(Continued from page 1)

**SCIENTISTS IDENTIFY INHERITED PROSTATE CANCER GENE**

The first major gene mutation associated with an increased risk for hereditary prostate cancer has been identified by scientists. Men who inherit the mutation in the HOXB13 gene have a 10 to 20 times increased risk of developing prostate cancer, according to the study in the 12 January 2012 issue of the New England Journal of Medicine.

The HOXB13 gene plays an important role in the development of the prostate during the fetal stage and in prostate function later in life. The discovery of this gene mutation may help improve understanding about the development of prostate cancer and which men may require early screening for the disease, according to the team led by investigators at the Johns Hopkins University School of Medicine and the University of Michigan Health System.

The researchers analyzed DNA from the youngest prostate cancer patients in 94 families that had multiple cases of the disease among close relatives, such as fathers, sons and brothers. Members of four different families were found to have the same mutation in the HOXB13 gene. All 18 patients in those four families had the mutation.

The investigators then looked at 5,100 men who had been treated for prostate cancer and found that 1.4 percent (72) of them had the same HOXB13 gene mutation. The men with the mutation were much more likely to have at least one first-degree male relative (father or brother) who also had been diagnosed with prostate cancer.

When they looked at a control group of 1,400 men without prostate cancer, only one of the men had the mutation. The researchers also looked at data from men enrolled in studies of early-onset or familial prostate cancer. “We found that the mutation was significantly more common in men with a family history and early diagnosis compared with men diagnosed later, after age 55, without a family history. The difference was 3.1 percent versus 0.62 percent,” Dr. Kathleen Cooney, a professor of internal medicine and urology at the University of Michigan Health System, echoed the excitement voiced over the primary survival results.

**HOW EXERCISE MIGHT REDUCE PROSTATE CANCER PROGRESSION**

A new study suggests that vigorous physical activity will offer protection against prostate cancer progression because of its effects on DNA repair and cell-cycle pathways. These findings were highlighted during a presscast in advance of the 2012 Genitourinary Cancers Symposium (GUCS), held in San Francisco, CA. It was organized by the American Society of Clinical Oncology, one of the meeting’s sponsors.

Senior author June Chan, ScD, associate professor of epidemiology, biostatistics and urology at the University of California, San Francisco and colleagues, conducted a study in 70 men with low-risk prostate cancer who were undergoing active surveillance and who had been taking part in a study on nutritional supplements. The team looked at gene expression in biopsy specimens and found differences between the 23 men who reported exercising vigorously for at least 3 hours per week and the 47 men who reported less.

The men who exercised had a differential expression of 184 genes; the upregulated genes included well-known tumor-suppressor genes such as BRCA1 and BRCA2, Dr. Chan reported. The gene-set analysis also revealed that cell-cycle and DNA repair pathways were positively modulated in men who reported participating in vigorous physical activity for at least 3 hours per week, compared with those who reported less, she added.

However, she noted, “there were no significant genes or pathways associated with the physical activity when we compared men reporting engaging in any vigorous physical activity [and those reporting engaging in] none, suggesting that a certain threshold of intensity or duration may be important.”

“These preliminary data suggest that DNA repair in the prostate gland is one mechanism through which vigorous physical activity may protect against prostate cancer progression,” Dr. Chan said. She emphasized that the study is small so the finding could be due to chance, and that potential confounding factors were not considered.

*Medscape Medical News, 1 February 2012*
but every now and then we will see an extreme value. So, we never make a major patient decision on one lab value without repeating it.

In order to call recurrent disease, you would not only have to have a consistently detectable PSA, but it would have to show a progressive increase. Furthermore, the increasing PSA would have to show a consistent doubling time indicating exponential growth. The latter is an important criterion as many men have a PSA that is detectable after RP because normal prostate tissue was left behind. With normal prostate tissue, you do not get a PSA doubling time. Instead, the PSA is usually stable or increases linearly rather than exponentially.

Finally, you are post-RP, so you should be tested with an ultrasensitive PSA assay. Standard PSA tests are optimized for PSA levels around 4.0 and it is quite inaccurate around 0.2 ng/mL. We regard the PSA test you are using as being next to worthless in this low range.

I suspect you may well be cured and that you had a single result that was a lab error. In any case, if you follow the guidelines we have provided, you will be able to determine if you have recurrent disease and gain an accurate measure of how fast it is growing.

Bottom Line: Men drinking low-fat milk (about a serving a day) compared to those that drank less (little to none daily) had a non-significant reduced risk of prostate cancer progression. In reality, what this means is that milk and dairy intake after a prostate cancer diagnosis does not seem to be correlated with a higher risk of fatal prostate cancer. However, whole milk might have some issues (Note: obvious teaser to get you to read the whole brilliant column of Doc Moyad).

I cannot believe Tom Brady lost another Super Bowl (my world is crumbling around me), but wait, Mario Manningham caught the pass that gave the Giants the chance to win the game and he used to also play for the University of Michigan (my world is no longer crumbling around me). In this issue, I want to talk about beer and football but the folks at Us TOO won’t let me because they are control freaks, and want me to talk about prostate cancer.

Okay, there was this new study of Health Care Professionals with prostate cancer (no kidding), and researchers followed close to 4000 men with this condition. Men with a greater compared to a lower intake of low-fat milk had a non-significant lower risk of prostate cancer progression. Men with the highest (>4 servings/week) whole milk consumption compared to men with the lowest (0-3 servings/month) had a significantly higher risk of cancer progression.

Why was this? Could it be that whole milk has more saturated fat and more calories compared to low fat milk? Men that consume higher fat milk on average in the US tend to (on average, don’t shoot the messenger folks) be more likely involved in other unhealthy behaviors (aka smoking…). And men that consume less fat in their milk are arguably more likely involved in multiple healthy behaviors. You see this is what these studies cannot capture, which is all the things men are doing right and wrong for their health apart from drinking milk and a few other things.

So, if you decide to drink low fat milk after this article it will probably do nothing for you. However, if you decide that you are going to exercise more in 2012, lose weight, reduce your waist size, blood pressure, cholesterol and stress, improve your mental health and drink more low fat or almond milk then it is more likely that you will benefit in 2012. Sounds simple, but less than 5% of Americans are able to follow these basic rules. And, if you are in the minority that are taking all these multiple steps to improve your health and you still want to drink some whole milk… well good for you because I still believe it is the sum of what you do in life that is greater for your health compared to just 1 or 2 things in excess. You probably already HERD that I use a low 40-calorie almond milk right now on my cereal, but that is because I had a previous BEEF with a COW that looked at me funny when I was driving my BULL-DOZER near him….man that cow was MOO-dy! Oh well, just an UDDER day in my world!

Reference:
THE BOTTOM LINE: Alpharadin is likely to become another option for preventing skeletal related events in men with bone metastases and may offer fewer serious side effects compared to XGEVA and Zometa.

Illustrating the concern about the side effects of XGEVA is a recent recommendation against approval of the drug in men with non-metastatic disease. Although it did delay developing new metastases, it did not improve survival and the frequency of developing osteonecrosis of the jaw was about 5%.

An interesting letter has appeared about whether Medicare will continue paying for PSA screening given the recent report by the USPTF. On congressman Kucinich’s website, it states that the head of HHS, Dr. Sibelius has agreed to overrule the report and keep paying for PSA. What is unclear, however, is whether this is indeed accurate since the final report has not even been submitted.

THE BOTTOM LINE: Considerable controversy has surrounded the USPTF report on prostate cancer screening. We will have to wait until there is clear confirmation about what the government plans to do.

Another study reported the use of flutamide and finasteride in men with a rising PSA level after previous treatment. The results are interesting, but unfortunately, there is no way to make any conclusions about the true effectiveness of this treatment. The study is relatively small, there is no control group and the added value of finasteride over flutamide alone cannot be determined. Only a properly done randomized study will permit a true assessment of this treatment.

Combining finasteride and flutamide might become a useful therapy for men with a rising PSA but at this time it is impossible to assess if patients really benefit.

The debate seems never ending over whether radical prostatectomy, EBRT or brachytherapy is the best treatment for localized disease. The primary reason is an absence of randomized trials. Without them, the best information comes from case series as was done in the study of Medicare patients. It found that brachytherapy had the fewest complications needing treatment and it was the least costly, while EBRT had the most complications and was the most costly. Unfortunately, caution is needed in drawing any conclusions from this study for several reasons. First, since it is not randomized, some factors might have biased the results. Secondly, IMRT is in much greater use now that could result in fewer side effects. Thirdly, the study only looked at treatment interventions so side effects not requiring an intervention might have changed the results.

THE BOTTOM LINE: Until a randomized study is performed, a true comparison of the different treatments cannot be done and the debate will remain.

Many men with prostate cancer ask what they can do to help themselves. Vitamins, herbs, supplements and exercise are often recommended, although no well done studies have been done to know if they really offer any benefit. The very preliminary study about exercise suggested that gene expression is altered in men getting at least 3 hours of vigorous exercise per week. Unfortunately, there are so many questions that need to be addressed before we will find out if this is indeed beneficial. For example, what exercise is really considered vigorous? Does it mean raising one’s heart rate to a certain level? Are all types of exercise the same? Are anaerobic exercises like tennis the same as aerobic exercise like cycling and what about weight training?

THE BOTTOM LINE: Exercise has many health benefits and sadly, not enough prostate cancer patients do regular exercise. Whether it helps against their cancer will require much more research.
with the US FDA, which has granted fast-track designation for this indication. This is a therapeutic niche that has been filled with new agents over the past year or so for use in post-docetaxel CRPC. These include abiraterone (Zytiga®), cabazitaxel (Jevtana®) and the vaccine sipuleucel-T (Provenge®), which were approved for use in this patient population in 2010. The radiopharmaceutical 223radium chloride (Alpharadin®), will soon be submitted to FDA for use in CRPC patients with bone metastases. During the presscast, prostate cancer expert Oliver Sartor, MD, medical director of the Tulane Cancer Center in New Orleans, LA, noted that although each of these products has shown significant improvement in overall survival in CRPC, research on combinations or sequential use of these agents “may add even more value” and lead to even more important steps forward. Currently, there are no clear guidelines about which agent should be used when, but there is plenty of discussion.

Medscape Medical News, 1 February 2012

XGEVA BENEFITS/RISKS
(Continued from page 1)

non-bony areas.” Wilson said that the drug’s risk make it safer for patients to continue only taking Xgeva when tumours already have spread to their bones. “This isn’t a question of whether this drugs works. The question is when is the most effective time to give it,” he added. Amgen said it will continue discussions with FDA regarding its filing. CMO Sean Harper noted that “the development of bone metastasis is an irreversible, life-changing event for men living with CRPC and is associated with significant and progressive morbidity,” adding “Xgeva is the first agent to prolong bone metastasis-free survival and addresses this important unmet medical need.”

A final decision is expected by April 26. Xgeva and Prolia have had combined sales of approximately $550 million last year. BMO Capital Markets analyst Jim Birchenough forecast that Xgeva sales would reach between $3 billion and $4 billion in 2015, and suggested that if the company fails to win approval in the pending CRPC indication, lost potential revenue would be about $1 billion.

www.PharmPro.com, 9 February 2012

HEREDITARY PROSTATE CANCER
(Continued from page 5)
of Michigan Medical School, and one of the study’s two senior authors, said in a news release. “It’s long been clear that prostate cancer can run in families, but pinpointing the underlying genetic basis has been challenging and previous studies have provided inconsistent results added fellow senior author William Isaacs, a professor of urology and oncology at the Johns Hopkins University School of Medicine. While the HOXB13 gene mutation may account for only a small number of prostate cancer cases, it may provide clues about how this cancer develops and help to identify a group of men who might benefit from early or additional prostate cancer screening, researchers said.

HealthDay News, 11 January 2012