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FROM THE DOCTOR:
PHYSICIAN COMMENTARY ON SELECTED ARTICLES IN THIS MONTH’S HOTSHHEET

By Gerald W. Chodak, MD

This month brings our attention to one of the most important ways to make progress in the battle against prostate cancer, the clinical trial. For many men faced either with an unfavorable pathological finding after surgery, or more commonly progression of advanced disease, the optimal therapy remains unclear. Fortunately, scientific knowledge is increasing rapidly leading to an increased understanding of how tumors grow which offers new opportunities to stop their growth. In Still Rolling we have a discussion of several of these new programs and the most important message for the patient is whenever possible get enrolled in an appropriate clinical trial when conventional therapies no longer are adequate. The hallmark is the randomized study which does require that some men will either get the conventional treatment being used rather than the newer experimental one, or in some cases a placebo or inactive medication. Often patients are reluctant to participate in a study using a placebo for fear that they will not receive the newer medication. But keep in mind that at least the odds are 50:50 or in some cases

(Continued on page 2)

SENATORS ADVOCATE CONTINUED PAP ASSISTANCE FOR MEDICARE BENEFICIARIES

Senators Chuck Grassley (R-IA), Max Baucus (D-MT.), Orrin Hatch (R-UT) and Jay Rockefeller (D-WV) petitioned HHS Inspector General Daniel Levinson to address drug companies participation in patient assistance programs (PAPs). The HHS should provide definitive guidance to drugmakers, said the senators, ensuring that patients with extraordinary healthcare needs remain able to participate in PAPs even after signing up for the new Medicare prescription drug benefit. Help may be discontinued for certain patients the senators worried, after May 15 – the deadline for Medicare recipients to sign up for the new benefit.

"PAPs provide free or subsidized medications to thousands of individuals, including Medicare beneficiaries, who might not otherwise be able to afford their prescription drugs, even if they are enrolled in the new Medicare prescription drug benefit," states the letter. "We have been pushing for a resolution on this issue since November," added Rockefeller. "We are less than a month away from having some drug

(Continued on page 2)
US TOO INTERNATIONAL has received Charity Navigator’s highest rating for sound fiscal management. Less than a quarter of the charities in America receive this exceptional rating.

PAP ASSISTANCE (Continued from page 1)

companies terminate these vital programs … Nothing short of an immediate and complete clarification of these rules is acceptable.”

In response, Levinson’s office issued an advisory opinion to one drug company — its name withheld from the public — that had requested PAP clarification. The senators largely welcomed this action.

"I'm glad the HHS … was able to advise one drug manufacturer on how to continue its patient assistance program in conjunction with the … benefit," noted Baucus. "It's good that the pharmaceutical manufacturer involved has found a way to continue providing this much-needed assistance, and I hope that others in the industry can do the same so that … Medicare beneficiaries can get the drugs they need."

There are roughly 180 PAPs in effect, providing billions of dollars in free medicine to beneficiaries. These programs help fill gaps in coverage for patients facing out-of-pocket costs but do not qualify for Medicare's low-income assistance.

FDAnews Drug Daily Bulletin 21 April 2006

GTx ATTAINS ENROLLMENT GOAL FOR PIN TRIAL

GTx has attained its enrollment goal for a pivotal Phase III clinical trial of Acapodene for the prevention of prostate cancer in men with high-grade prostatic intraepithelial neoplasia, or PIN.

This is the largest-ever prospective clinical study of high-grade PIN, with more than 1,260 men participating in the randomized, placebo-controlled, double blind trial.

Patients in the clinical trial will be randomized to receive daily for three years either Acapodene in a 20 mg dose or placebo. The primary endpoint is a reduction in prostate cancer incidence.

FDAnews Drug Pipeline Alert 4 May 2006

FROM THE DOCTOR (Continued from page 1)

even greater that the active medication will be received. Also, without taking that risk, there is a 0% chance of getting the new medication. Furthermore, a placebo is used only when there is no medication that has already shown to benefit patients. Researchers would never withhold a medication known to be effective just to try out something new. So the best advice is whenever appropriate, keep abreast of the latest studies underway as summarized in this article, ask your doctor if he/she is aware of any or check in with the National Cancer Institute through their website where studies are summarized.

As an example, the study described in this issue involves an oral agent DN-101 that is an oral anti-cancer agent that is a higher dose of a hormone, calcitrol that leads to higher levels of vitamin D in the bloodstream. Preliminary studies have shown that Vitamin D interferes with the growth of prostate cancer. In this study, the experimental drug will be added to the proven drug, Taxotere, to see if survival of men can be further increased. So this trial will give all men the conventional Taxotere and some of the men will in addition receive the experimental drug. Sites performing the study can be found by checking on the website www.ascent-2.com.

The article about urinary incontinence is a very worthwhile contribution providing more education about this troubling problem that can occur following surgery, radiation or seed implantation. One of the limitations throughout the country is that doctors may not devote enough time to explain these terms and educate patients about this problem. Also lacking is a true explanation of the chances it will occur for each treatment that greatly depends on the doctor performing the treatment. All patients should be encouraged to ask their treating physician for specific numbers about this risk that occurs specifically for the physician in charge. In many cases, men might make different choices if those numbers are unacceptable. Fortunately, if the problem does occur, there are many options available to improve a man’s quality of life. If you have encountered this problem and you are not making progress then you should feel entitled to make sure all options are being explored.
Scientists are reporting that they have detected a variant gene associated with prostate cancer, a finding that may make possible a diagnostic test to help decide which patients are the best candidates for aggressive treatment. The discovery by Decode Genetics, a gene-finding company based in Iceland, may also help explain why African-Americans, in whom the variant is more common, have a greater incidence of the disease.

Prostate cancer is a common disease with many different causes, both genetic and environmental. Detection of the underlying genes is difficult because each gene seems to only manifest a small effect. Several candidate genes have been identified in one family or population, but have generally not been confirmed by researchers trying to replicate the finding in other populations.

The new variant, to be described Monday in the journal Nature Genetics, was first found in Icelandic men and then detected in Sweden and in two populations in the United States.

David Altshuler, a medical geneticist at the Broad Institute in Cambridge, said the result was statistically convincing and, because it was tested in four populations, "a model for how these things should be done."

The variant is carried by about 13 percent of men of European ancestry. It raises the risk of getting prostate cancer by 60 percent, compared with men who are not carriers, and accounts for about 8 percent of all cases, says a team of scientists led by Laufey Amundadottir of Decode Genetics.

Among African-Americans, the variant carries the same risk but is twice as common. This could explain "a significant part" of the reason that prostate cancer is more common in this population, said Kari Stefansson, Decode’s chief executive.

Dr. Stefansson added that the variant was "the first major gene in prostate cancer and the first to be replicated in many populations."

William B. Isaacs, a prostate cancer expert at Johns Hopkins University, called the new finding "very exciting" and added that until now, "there haven't really been any clear cut examples of genes identified by one group and reproduced across multiple study populations."

The new variant was not especially common in Icelandic men with a harmless enlargement of the prostate gland, called benign prostatic hyperplasia, indicating that its association was just with malignant forms of the disease. Dr. Stefansson said this might explain why African-Americans more often died from the disease, in addition to having a higher incidence than European-Americans.

The company plans to develop a diagnostic test, based on the new variant, to help physicians decide how aggressively to treat the disease, especially in men over 70, on the assumption that men who carry the variant are more likely to develop serious cancer.

Many men in this age group "have competing morbidities," Dr. Isaacs said, and go on to die of other things, in which case it would be best to leave the prostate cancer untreated. But in some, the cancer is malignant, and if such an outcome could be predicted, aggressive treatment like radiation therapy or removal of the prostate gland would be more worthwhile.

Both Dr. Isaacs and Dr. Altshuler said that the idea of a diagnostic test was reasonable but that additional clinical studies would be needed to show if the information would be of practical importance in the clinical setting.

The new variant discovered by Decode lies at a site on the DNA of Chromosome 8. Until now no gene has been recognized at this site, but Decode researchers have found hints of one that is active in the prostate gland. It is unlike any other known gene, so it is not possible at this time to say what the gene normally does or how the new variant contributes to prostate cancer.

\textit{New York Times, 7 May 2006}
LIVING WITH URINARY INCONTINENCE  By Ralph Alterowitz, MEA and Dr. Carol Partington, DVM
Excerpted from the book A Patient’s Guide—Urinary Incontinence Control Using External Urethral Compression Devices

The purpose of this article is to educate men experiencing urinary incontinence, whether temporary or long-term, to enable them to cope with this condition. A general discussion of incontinence, its effects on the quality of life, and the options for managing and treating it, are presented.

Definition
Urinary incontinence may be defined in various ways. Perhaps the most comprehensive definition is “a condition in which involuntary loss of urine is a social or hygienic problem and is objectively demonstrable” (the International Continence Society Standardization Committee). More succinct, and more relevant to every day living may be “involuntary loss of urine that is sufficient to be a problem” (Centers for Medicare and Medicaid Services). The “problem” is neither single nor simple and actually affects many aspects of life: medical, economic, psychological, and social.

Consequences of Incontinence
Among the medical consequences are rashes, pressure sores, and skin and urinary tract infections due to prolonged contact with urine. Additionally, injuries may occur due to falls associated with trying to reach the bathroom in a hurry, especially at night. The economic costs include not only the cost of absorbent products, external control devices such as clamps or condom catheters, and/or medications, but the cost of skin care products, increased laundry, and replacement of ruined clothing or furniture. Also, patients may be unemployed, underemployed, or forced into early retirement due to their need to be near bathroom facilities and to use the facilities frequently. Psychologically, incontinence may lead to low-self esteem since in our society toilet training is accomplished at an early age, and from childhood we are taught that having an “accident” is shameful. Depression may occur, especially in older patients who may think that becoming incontinent is a natural consequence of aging. It is not, though it may be an indication of worsening health. Anger, too, may result since loss of bladder control may cause a feeling of loss of control of other aspects of life; this is especially true of active persons forced to alter or curtail their usual activities. Adults who become incontinent may become socially withdrawn and isolated, as embarrassment and fear of having an accident, and the inconvenience of managing the condition leads to avoidance of social activities. Self-consciousness and anxiety about appearance and odor may also lead to social withdrawal.

Incontinence is not an isolated or rare problem; an estimated twelve million Americans suffer from this condition and the actual number is probably much greater. Of this number, about three million are men. People suffering from incontinence often feel embarrassed about their problem and cut themselves off from their friends and even their families. However, incontinence is not as simple as just being unable to control urine flow; it is a medical problem that should be discussed with a doctor. Avoiding discussion of the problem with a health care professional deprives incontinence sufferers of the opportunity to better manage their situation and greatly improve their quality of life.

There are varying degrees of incontinence ranging from mild (occasional loss of a few drops of urine), moderate (loss of small to moderate quantities of urine in certain situations or while undertaking certain activities) to severe (loss of moderate to large quantities of urine frequently, or daily). The best treatment or management program will differ based on the degree of incontinence and the type of incontinence, which is discussed below.

Types of Incontinence
Although there are various ways to classify incontinence, there are three basic types that will be discussed here: stress, urge, and overflow.

Stress incontinence – Urine leakage that occurs with increased pressure on the bladder due to coughing, straining, lifting, or other activity is termed stress incontinence. The activity need not be strenuous; leakage may occur due to the “stress” of gravity, such as when standing up from a seated position. In men, damage to the valve muscle (sphincter) of the bladder during prostate surgery is the most common cause of stress incontinence. During prostatectomy (removal of the prostate) the urethra (the tube which carries urine out of the body) is cut since it passes through the middle of the prostate and the prostate is very tightly attached to it. The surgeon then reconnects the urethra to the bottom (neck) of the bladder. A catheter is inserted to permit urine flow while the urethra heals.

After the urethra is healed, which takes two to three weeks, the catheter is removed. It is important for men to realize that they will not know immediately after surgery if the valve muscle has been damaged. In fact, more than 95 percent of men who have had surgery are incontinent at this point and may remain so for two or more months after the catheter is removed. Brachytherapy (radioactive seed implants) may result in injury and scarring of the sphincter (valve) muscles at the neck of the bladder; up to seven percent of brachytherapy patients may experience long-term incontinence.

Urge incontinence – Urine leakage that occurs when a person feels a strong need to urinate and cannot reach a bathroom in time is called urge incontinence. The urge to urinate is due to contractions of the bladder muscle; these contractions will begin when the bladder is less than half full of urine and are normally voluntarily suppressed until the person decides to void. With urge incontinence, the contractions cannot be suppressed, and urine will begin to leak. This type of incontinence is sometimes referred to as an “overactive” bladder. In men this may be caused by bladder irritants, such as caffeine or aspartame (NutraSweet®, Equal®) or by an enlarged prostate blocking the flow of urine through the urethra. About 17 percent of men who have undergone a Trans Urethral Resection Procedure (TURP) to reduce the size of the pros-
tate have been shown to experience incontinence due to the procedure. Urge incontinence may also be a side effect of radiation therapy, particularly external beam radiation therapy with a dose that exceeds 70 Gy (Gy stands for gray, a standard unit for measuring the absorbed dose of radiation).

Overflow incontinence – is caused by a blockage in the urethra or by weakness in the bladder muscle. If the urethra is blocked, by an enlarged prostate for example, the bladder cannot empty normally and becomes too full. As the amount of urine in the bladder increases it eventually causes the sphincter (valve muscle) to stretch and allows a small amount of urine to dribble out.

A weak bladder muscle cannot contract strongly enough to force the urine out of the bladder and once the bladder becomes overly full, small amounts of urine will leak past the sphincter. This type of incontinence is more common in men than in women and is frequently due to an enlarged prostate. Other causes of overflow incontinence are diabetes, heavy alcohol use, and other conditions that result in decreased nerve function such as multiple sclerosis, polio, or trauma to the pelvic region.

Mixed incontinence – is a combination of stress and urge incontinence, i.e. the sphincter (valve) muscles are weak, and there are uncontrollable urges to urinate.

Treatment-induced incontinence – is clearly the major cause of urinary incontinence in men treated for prostate cancer. Radical prostatectomy is responsible for the majority of cases of incontinence, but radiation therapies and cryotherapy (freezing of the prostate gland) also carry some risk of causing incontinence.

Treatments / Management

Urinary incontinence may be treated and managed by a number of methods; in many cases a combination of these may result in the best outcome. The major ways to manage incontinence are dietary management, physiotherapy techniques, surgical intervention, supportive measures and medications.

Dietary considerations – These include avoiding bladder irritants, such as caffeine, aspartame (Equal, NutraSweet), and acidic foods (such as citrus and tomatoes). Managing fluid intake, for example, limiting fluids before going to bed, may be helpful. Management does not mean restriction; in fact, it is important not to become dehydrated. One effect of dehydration may be constipation, which itself will worsen urge incontinence, as the bowel will press against the bladder.

Bladder training – This involves planning to urinate at regular scheduled intervals, and gradually increasing the interval between voids.

Kegel exercises – These exercises strengthen the pelvic floor muscles, especially the pubococcygeus muscle, which provides support for the abdominal organs. Strengthening this muscle improves the function of the urethral and rectal sphincters.

Biofeedback – Biofeedback uses computer screen graphs and sounds to help patients locate and train pelvic muscles by monitoring muscle activity and providing immediate feedback.

Surgical treatments – include perurethral (next to the urethra) injections of bulking agents, a bulbourethral sling, or implantation of an artificial urinary sphincter.

Supportive interventions – These include periodic catheterization, use of absorbent pads, condom-catheter collection systems, and external urethral compression devices or clamps.

Medications – These drugs act directly on the bladder muscle (musculotropic) to cause it to relax. Examples of these drugs, used to treat urge incontinence, are Detrol® (tolterodine), Ditropan® (oxybutinin) and Vesicare® (solifenacin). These drugs cause relaxation of the bladder muscle, thus reducing the feeling of urgency.

The drug imipramine, an antidepressant sold under many trade names, is used to treat cases of both urge and stress incontinence. Mild stress incontinence may be controlled by over-the-counter decongestant agents, such as Sudafed-PE® (phenylephrine). Always check with your doctor before using one of these over-the-counter medications since they may interact with other drugs you are taking or affect other health conditions.

External Urethral Compression Devices, or Clamps

The external urethral compression device, or clamp, has existed in some form since the 18th century. A French medical journal in 1731 described a metal, hinged clamp, covered with velvet and using a ratchet device for attachment, that was similar in size and appearance to the Cunningham clamp in use today.

Despite this long history many men are apparently still unaware of these devices, according to the coordinator of the largest prostate cancer support group in New England (reported in 2000 in the Walter Reed Army Medical Center [WRAMC] US TOO! Newsletter). This may be due in part to the reluctance of some medical professionals to recommend using clamps, as incorrect use may be at the very least uncomfortable, and at worst cause damage to the penis and the rest of the urinary system. However, used correctly, a clamp may provide a substantial improvement in the quality of life for many men suffering from any degree of urinary incontinence for any length of time.

Several different designs of clamps are currently available; they are relatively inexpensive, non-invasive, adjustable, and reusable for varying periods of time. All clamps work by compressing the urethra, the tube which carries urine out of the body and which is located along the underside of the penis.

However, for a clamp to put pressure on the urethra, the entire circumference of the penis must be compressed to some extent. Thus, in addition to pressing on the urethra, a clamp also puts pressure on the arteries, veins, and nerves that nourish and provide sensation to the penis. Many of the clamps are designed to minimize this; the correct design is the one that is most comfortable for the wearer.

Usage Considerations, Instructions, and Precautions

- Clamps must be released every 2–4 hours to empty the bladder. Allowing urine to remain in the bladder
A CIRCLE OF LOVE IN GALVESTON, TX

“Bill thought it was one of our best meetings ever and stimulated interesting discussion by all,” says Galveston Chapter Leader, Barb Lober. She was speaking of her husband and co-chapter leader’s response to a recent meeting at which they used the Circles of Love Care Kit and Discussion Guide.

“I think the wives see [Circles of Love] as a way to encourage their husbands to communicate better with them, or at least to understand the caregiver concerns/ issues and have a couple’s discussion. Also, our members enjoy the Circles of Love format as tool to get to know each other better.”

Galveston is one of a growing number of chapters using the Circles of Love Care Kit and Discussion Guide in their regular chapter meetings, to rave reviews. As recent Circles of Love grant recipients, the Galveston chapter received FREE Circles of Love materials to use in their chapter meetings.

Barb reports the timing of the grant was most fortunate. “I had scheduled a program for caregivers and survivors, and called the Us TOO office to order kits and extra books to have on hand.” As the first grant recipients, they received materials for FREE. The materials arrived promptly and she immediately put them to good use.

Barb explains, “Our group usually has about 15-20 in attendance, mostly couples. So, we turned our regular monthly meeting into a discussion group. We had 16 in attendance, seven couples and two guys there by themselves. Because most of our members have been treated and are in remission now, I chose to use the ‘Living with Prostate Cancer’ section of the Circles of Love Collection, because is seemed most applicable to most of our members.”

“We just started with the first story in that section, Maureen and Jim’s story. I read the story first,” explained Barb, “and then I asked the group each question in the discussion guide. It served as a good tool to get everyone engaged in sharing their experiences. We had a lot of participation from the group and want to have some other meetings devoted to this format.”

Looking ahead, Barb shares, “We plan to have other similar Circles of Love meetings every 3-6 months. It works as a good filler for us whenever getting a speaker is difficult. I am also working with the Houston group and would like to have a much bigger combined event on this topic.”

Us TOO congratulates the Galveston chapter for their continued efforts to serve the entire prostate cancer community, patients and their loved ones!

Circles of Love Care Kit was released in June 2005. The Circles of Love Discussion Guide was distributed to all chapters in early February. The Circles of Love Care Kit and all its individual components are available for purchase by calling the Us TOO offices at 800-808-7866.

For additional information about The Circles of Love Program, please contact Elizabeth at 320-980-0437 or Elizabeth@ustoo.org.

URINARY INCONTINENCE

(Continued from page 5)

for prolonged periods increases the risk of urinary tract infections.

• Do not use a clamp in conjunction with other incontinence devices indwelling catheters, or with implanted penile prostheses.

• Contact your doctor immediately if any swelling, bruising, discoloration (change in color), or sores develop on the penis while using any clamp. In many cases simple adjustments and/or more practice using the clamp will solve the problem.

• Do not use near open sores. After sores are completely healed, the clamp may be used again.

• Patients with altered mental status should not wear a clamp.

• Do not hesitate to contact your physician if you have any concerns or questions about using a clamp.

• If a clamp is not properly positioned, secured too tightly, or left on too long it can cause swelling, bruising, and ulceration (sores) on the penis. If ignored, deep tissue necrosis (destruction of the tissues inside the penis) may occur.

• When using a clamp, it is important to be aware that urine will begin to flow immediately when the clamp is released, and the flow will be under pressure. This may make control of the urine stream erratic, and result in wetting the clamp or clothing.

• Use a pad. Use of an absorbent pad in addition to the clamp is suggested by some manufacturers, and may provide extra peace of mind.

The “best” clamp is the one that provides an appropriate level of protection and comfort as determined by the wearer. It is important to be aware that over the course of a 24-hour day the penis changes in length and diameter (turgidity); these changes will affect the amount of compression and therefore the comfort and security of these clamps. Readjustments will be necessary during the day and should be made when needed. Clamps with thick foam padding will be least affected as the foam will compress and expand in response to these natural changes. However, since all clamps must be released every few hours to void urine, the user will make the adjustments at these times and no additional effort will be required.

When deciding to use a clamp for incontinence control, several criteria need to be carefully considered; especially comfort, cost, conditions or activities during which the product will be worn, and insurance coverage. The most important consideration should be comfort. There is no point in purchasing a device that is so uncomfortable that it will not be used. Think about the types of activities you plan to do while wearing the clamp. Some users may find that they are more comfortable with one type of clamp for strenuous activity, and a different type for less active periods. Also note that some clamps are not recommended for use during sleep; those that are labeled for use during sleep state that the clamp should be applied more loosely when sleeping than when used while awake and active.

Next, consider the cost. “Disposable” clamps can generally be worn for at least several days and range in cost from about $10.00 up. Some of these are sold in multi-packs, which reduce the cost per unit. The cost of reusable clamps (that last from 3 months to
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- Baseball Hats – Navy or white, $16.00 ea
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- Us TOO STRIVE Initiative Awareness Wristbands – $1.00 ea

To order, visit www.ustoo.org

Proceeds from all items sold benefit Us TOO’s FREE programs, support services and educational materials for prostate cancer patients and their families
more than a year) ranges from $33.00 to $80.00 each. These must be kept clean and can be washed with mild soap and water and allowed air dry. Insurance may cover all or part of the cost for up to 4 reusable clamps per year, if the clamp has FDA approval and is obtained through a physician or pharmacy. Check with your insurance company to find out if they will cover the cost of a clamp and to find out what information you need to provide to receive reimbursement. An estimate of the cost per year (i.e. how many units would be purchased over a 12 month period), rather than simply the cost per clamp provides a more accurate cost.

For men suffering from incontinence, whether temporary or chronic, an external urethral occlusion device can provide effective, affordable management of the problem and permits an active lifestyle.

This article was prepared by Ralph Alterowitz, MEA, certified sex counselor (AASECT), and co-author of Intimacy with Impotence and Dr. Carol Partington, D.V.M. More information is available at <www.renewintimacy.org>.

**US TOO INTERNATIONAL: OUR MISSION**

Communicate timely, personalized and reliable information enabling informed choices regarding detection and treatment of prostate cancer.

**NOVACEA INITIATES PHASE 3 CLINICAL STUDY OF DN-101 FOR ADVANCED PROSTATE CANCER**

Novacea, Inc. has announced the initiation of ASCENT-2, its pivotal Phase 3 clinical study evaluating the combination of the Company’s novel oral anticancer agent, DN-101, and Taxotere® (docetaxel) in men with prostate cancer for whom hormonal therapy is no longer working, also known as androgen-independent prostate cancer (AIPC). This randomized, controlled, multinational study is seeking to enroll approximately 900 patients at over 125 medical centers in the US, Europe and Canada. Patients, or physicians interested in referring a qualified patient, can now go to <www.ASCENT-2.com>, which was launched in April to facilitate trial awareness and enrollment.

According to the American Cancer Society, prostate cancer is the second leading cause of cancer death in men with approximately 232,100 new cases and 30,400 deaths in the United States in 2005. The mortality from this disease is expected to rise significantly with the aging of the “baby boomer” generation. The Prostate Cancer Foundation forecasts that without new interventions the number of deaths from prostate cancer in the United States will grow to approximately 68,000 annually by 2025.

“Results from the 250- patient, Phase 2 ASCENT clinical study, showed that DN-101 appeared to improve survival while reducing some of the serious side effects of chemotherapy,” said Howard Scher, M.D., Chairman of the ASCENT-2 study and Chief of the Genitourinary Oncology Service at Memorial Sloan Kettering Cancer Center. “The ASCENT-2 Phase 3 trial, is designed to determine if this regimen can improve outcomes for patients with advanced prostate cancer.”

DN-101 is Novacea’s proprietary oral, dose-intense formulation of calcitriol and the most potent ligand for the vitamin D receptor (VDR). DN101 works by binding to VDR which subsequently triggers cellular pathways that may stop cancer cell growth, leading to cancer cell death. DN-101 results in higher therapeutic blood levels than those achieved with previous forms of calcitriol. DN101 can safely deliver high, pharmacologically effective peak blood concentrations of calcitriol without inducing clinically significant hypercalcemia.

Company Press release—Novacea.com
11 April 2006