FDA AGREES TO SPECIAL PROTOCOL ASSESSMENT AMENDMENT TO D9902B "IMPACT" STUDY OF PROVENGE®

Dendreon Corporation (Nasdaq: DNDN) announced that it has reached an agreement with the U.S. Food and Drug Administration (FDA) under the Special Protocol Assessment (SPA) procedure to amend the design of its ongoing Phase 3 (D9902B) clinical trial of PROVENGE® (sipuleucel-T), the Company's investigational active cellular immunotherapy for the treatment of advanced prostate cancer. The SPA letter provides a written agreement between Dendreon and the FDA concerning the trial design and outlines definitive clinical objectives and data analyses.

The D9902B clinical trial was initiated in June 2003 under a SPA for the treatment of men with asymptomatic, metastatic, androgen-independent prostate cancer whose tumors had been classified with a Gleason score of 7 or lower. Based upon results of the Com-

(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.

The US TOO Prostate Cancer HotSheet is made possible by charitable contributions from

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PROSTATE CANCER PATIENT SUPPORT 1-800-80-US TOO

US TOO INTERNATIONAL (Continued from page 1)

pany’s two completed Phase 3 studies of PROVENGE®, D9901 and D9902A, the Company has amended the D9902B protocol, which will now be known as the IMPACT (IMmunotherapy for Prostate AdenoCarcinoma Treatment) study. Key amendments to the study include the following:

- Patients will now be eligible to enroll in the study, regardless of their Gleason Score;
- Patients with minimally symptomatic disease-related pain will be eligible for the study;
- The primary endpoint of the study is now overall survival, which will be an event-driven analysis, and time to objective disease progression is now a secondary endpoint;
- The trial is designed to enroll approximately 500 men in the study; and
- The primary statistical analysis to determine efficacy will be the Cox multivariate regression model. The same Cox model was used to analyze overall survival in the D9901 and D9902A studies.

Dendreon recently held a pre-BLA meeting with the FDA to review safety and efficacy data from its two completed Phase 3 clinical trials of PROVENGE®, D9901 and D9902A, in men with asymptomatic, metastatic, advanced prostate cancer. In these discussions, the FDA agreed that the survival benefit observed in the D9901 study in conjunction with the supportive data obtained from study D9902A and the absence of significant toxicity in both studies is sufficient to serve as the clinical basis of a BLA submission for PROVENGE®. As a result of that meeting, Dendreon recently announced plans to submit a BLA to the FDA in 2006 to market PROVENGE® for the treatment of men with asymptomatic, metastatic, androgen-independent prostate cancer.

"The amendment to the IMPACT study protocol should enable us to expedite enrollment in this study and will provide all qualified patients access to PROVENGE®, while we complete the BLA submission process," said Robert M. Hershberg, MD, PhD, Dendreon’s chief medical officer. "In addition to providing additional information for our safety database to support our BLA submission, the trial could provide us with an opportunity for an expanded label in patients with minimally symptomatic disease in the future."

About PROVENGE®
PROVENGE® is an investigational product that may represent the first in a new class of active cellular immunotherapies (ACIs) that are uniquely designed to stimulate a patient’s own immune system. ACIs hold promise because they may provide patients with a meaningful survival benefit with low toxicity. PROVENGE® targets the prostate cancer antigen, prostatic acid phosphatase (PAP), which is found in approximately 95% of prostate cancers.

PROVENGE® is in clinical development for the treatment of patients with early-stage and advanced prostate cancer. In clinical studies, patients typically received three infusions over a one-month period as a complete course of therapy.

About Dendreon
Dendreon Corporation is a biotechnology company whose mission is to target cancer and transform lives through the development of innovative cancer treatments. In addition to its immunotherapies in clinical and preclinical development for a variety of cancers, Dendreon’s product pipeline also includes monoclonal antibody and small molecule product candidates.

Dendreon Corporation
29 November 2005
**US TOO ANNOUNCES A NEW EDUCATIONAL BROCHURE**

You underwent a course of treatment in response to a prostate cancer diagnosis, in hopes of: a cure, preventing the spread of disease, eliminating symptoms in later stage, slowing the rate of the cancer’s growth, and/or extending life. Now, your PSA is rising, or you just learned that the prostate cancer it is not responding to treatment, or perhaps it has returned and even spread. This can be a highly emotional time for you and your loved ones. You may feel angry, sad, afraid and frustrated. You also may have many pressing questions, such as:

- Why isn’t treatment working?
- What does this mean?
- What options do I have?
- Where can I turn for support?

Us TOO is pleased to announce the release of an educational booklet designed for you and your loved ones. This booklet is called:

**WHAT NOW? Hope and options when experiencing a rising PSA, recurrence of prostate cancer, or when prostate cancer is not responding to treatment.**

At Us TOO, we know **YOU** are the key ingredient in your vitality, quality of life and prognosis. The purpose of this booklet is to provide information for you to discuss with your doctor and consider as you make decisions.

The booklet is filled with valuable information that will allow you to be informed and actively involved in your treatment and care, partnering with your doctor as your own best advocate. As always, this booklet is intended to be used only for educational purposes. It is not a substitute for informed medical advice from a physician.

Brochures will be distributed in January through the chapter network, and available be calling the Us TOO office at 1-800-80 Us TOO (or 1-800-808-7866.) The booklet will be downloadable from the Us TOO website <www.ustoo.org> as well.

**BONE TARGETED THERAPY**

(Continued from page 1)

Targeted agents should improve our ability to treat bone metastases. For example, a bisphosphonate (zoledronic acid, Zometa®) has been approved by the FDA for the treatment of bone metastases. Zoledronic acid may benefit patients with osteolytic metastases (such as in patients with multiple myeloma, breast, lung, and kidney cancers) as well as osteoblastic metastases (such as in patients with prostate cancer).

Prostate cancer is unique because a majority (about 65%) of patients have bone as the only site of metastasis. Furthermore, the bone metastases are predominantly osteoblastic (about 90%) in nature. Given the striking propensity for prostate cancer to develop bone metastases, we anticipated that radiopharmaceuticals (89strontium, Metastron®; 153samarium, Quadrantem®, which have been approved by the FDA for the treatment of bone pain, might improve the clinical outcome of patients with advanced prostate cancer.

Our preliminary results suggested that combining 89strontium with chemotherapy increased the survival of a selected group of patients with androgen-independent prostate cancer and bone metastases. A follow-up study indicates that this strategy of combining 89strontium with chemotherapy is safe.

We would like to inform the public that a confirmatory study (NCI-sponsored phase III clinical trial, MDA-3410) using this bone-targeted therapy for patients with advanced prostate cancer is currently open for enrollment at the M.D. Anderson Community Clinical Oncology Research Base (MDA-CCOP, www.mdanderson.org/ccop) and the Clinical Trial Support Unit (CTSU) offered by the National Cancer Institute (www.ctsu.org).

Eligibility criteria include:

- Androgen-independent prostate cancer
- Bone metastases on bone scan or CT scan
- Prior therapy with docetaxel (Taxotere®).

For more details, please contact Shi-Ming Tu, MD, by phone (713-563-7268), by Fax (713-745-1625) or by email stu@mdanderson.org, or Sandra Sinclair, RN, by phone (713-563-2948), by Fax (713-563-2956) or by email s.sinclair@mdanderson.org.

**References:**

**XINLAY ACCESS DENIED**  
*(Continued from page 1)*

based on the profile of the patient and the safety profile of the drug. Usually, single patient access is only authorized when the patient has exhausted all approved therapies.

“We’re very disappointed to hear that access has gotten even more difficult for this promising drug,” said Tom Kirk, President and CEO of Us TOO, the international support group for prostate cancer patients and survivors. “This will affect huge numbers of men, and once again shows that we need to be aggressive in our efforts to gain access to drugs during the research phase, to tell our story and explain what our needs are.”

“Prostate cancer patients should have access to as many options as possible,” says Dr. Jonathan Rubenstein of Maryland Urology Associates, “but men should exercise caution when seeking to take any drug that has not yet been approved. You have to weigh the risks of side effects against the potential benefits, particularly when there is no clear evidence of those benefits.”

Abbott says it continues to study Xinlay™ in an earlier stage population of patients, involving men with advanced prostate cancer that has not spread to the bone. Results of this study are expected by mid 2006.

**NPCC, 5 December 2005**

**CANCER’S ROAD MAP TO METASTASIS REVEALED**

Scientists have discovered how cancer spreads from a primary site to other places in the body in a finding that could open doors for new ways of treating and preventing advanced disease.

Instead of a cell just breaking off from a tumor and traveling through the bloodstream to another organ where it forms a secondary tumor, or metastasis, researchers in the United States have shown that the cancer sends out envoys to prepare the new site. Intercepting those envoys, or blocking their action with drugs, might help to prevent the spread of cancer or to treat it in patients in which it has already occurred.

“We are basically looking at all the earlier steps that are involved in metastasis that we weren’t previously aware of. It is complex but we are opening the door to all these things that occur before the tumor cell implants itself,” said Professor David Lyden, of Cornell University in New York.

"It is a map to where the metastasis will occur," he added in an interview.

**Landing Site for Cancer Cells**

Cancer’s ability to colonize other organs is what makes the disease so deadly. Once the cancer has spread beyond its original site it is much more difficult to treat.

In research reported in the journal Nature, Lyden and his colleagues describe what happens before the cancer cells arrive at the new site.

"The authors show that tumor cells can mobilize normal bone marrow cells, causing them to migrate to particular regions and change the local environment so as to attract and support a developing metastasis," Patricia Steeg, of the National Cancer Institute in Bethesda, MD, said in a commentary.

Cells at the site of the metastasis multiply and produce a protein called fibronectin, which acts like a glue to attract and trap the bone marrow cells to create a landing pad or nest for the cancer cells.

"These nests provide attachment factors for the tumor cells to implant and nurture them. It causes them not only to bind but to proliferate. Once that all takes place we have a fully formed metastatic site or secondary tumor," said Lyden.

"This is the first time anyone has discovered what we call the pre-metastatic niche." Without the landing pad, the cancerous cell could not colonize the organ.

"This opens up the door to new concepts of how metastasis is taking place. If we can understand all these multiple processes we can develop new drugs that block each step. That way we have a much better future than just trying to treat the tumor cell, which is almost like a last step in this process," he added.

*Reuter’s Health, 7 December 2005*

**NEW HOPE FOR PROSTATE CANCER PATIENTS WHERE RADIATION TREATMENT HAS FAILED**

Clinic Treats First Radiation Failure Patients In North America With Ablatherm® HIFU

William Orovan, MD, urologist and Medical Director of Don Mills Surgical Unit in Toronto announced today that they have commenced offering Ablatherm® HIFU treatment to prostate cancer patients whose radiation therapy has failed and the cancer has returned. Radiation treatment cannot be repeated if a patient has a recurrence. In the case of these patients, the non-invasive Ablatherm® HIFU treatment offers new hope to those men who previously had no curative option.

Ablatherm® HIFU is a highly precise procedure using high intensity focused ultrasound to eliminate prostate cancer. Ninety percent of patients can be treated by a single procedure usually lasting 1 ½ to 3 hours. Patients are generally discharged a few hours after the procedure. There are fewer side effects with the Ablatherm® HIFU treatment than conventional treatments such as radical prostatectomy, radiation, and cryotherapy.

Ablatherm® HIFU can be effectively used on patients with localized prostate cancer (clinical stage
How the HIFU Procedure Works

T-1 or T-2) who would otherwise be considered curable by radiation or radical surgery. Candidates for Ablatherm® HIFU must have had a recurrence of their prostate cancer without evidence of disease spread.

“Ablatherm® HIFU is a promising treatment option with a curative chance for patients with local recurrence after external beam radiotherapy,” said Dr. John Warner, an expert in HIFU technology.

“Clinical studies indicate a greater chance for patients with local recurrence after external beam radiotherapy,” added Dr. John Warner.

Ablatherm® HIFU has shown to be an effective treatment for recurrent prostate cancer. Published results in the Journal of Urology (April, 2004; 63: 625-9) showed that 80% (57 patients) of 71 consecutive unsuccessful external beam radiation therapy patients had negative biopsies at a mean follow-up time at 14.8 months (range 6-86 months). There was zero incidence of rectal fistulae. Unlike treatment with salvage cryotherapy or salvage surgery there have been zero incidents of rectal fistulae in patients treated with Ablatherm® HIFU since 2003.

To learn more about the Ablatherm® HIFU treatment, visit <www.hifu.ca>.

Maple Leaf HIFU Company
7 December 2005

MINIMALLY-INVASIVE PROSTATE CANCER THERAPY RESEARCH STUDY IN U.S.

A clinical trial to determine the effectiveness of focused ultrasound energy (HIFU) in treating patients who have locally recurrent prostate cancer. The device being studied to deliver HIFU is called the Sonablate® 500. This clinical trial is currently open to enrollment with the goal of generating clinical data to support approval by the US Food and Drug Administration.

Eligible participants must meet the following criteria:
- Have organ confined recurrent prostate cancer stage T1 or T2
- Be between ages 40 and 80
- Have a Gleason score of less than or equal to 7
- Have a PSA level between 0.05 ng/ml and 10 ng/ml
- Have previously failed radiation or brachytherapy as primary prostate cancer treatment
- Have a recent prostate biopsy that is positive for cancer cells

If you are interested in knowing more about the recurrent prostate cancer study, please visit www.ushifu.com, or call (888) 874-4384 and you will be directed to the study center nearest you.

Trial sponsored by FOCUS Surgery

MINIMALLY-INV ASIVE THERAPY RESEARCH STUDY IN U.S.

A published study in the Journal of Urology (February, 2004; 63(2): 297-300) showed that 93% of patients had negative biopsies and 87% had stable PSA levels (less than 1.0) at 22 months. Overall 90% of all patients treated with Ablatherm® HIFU require only one treatment and with complication rates lower than surgery, radiation, or cryotherapy.

Clinical Studies

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Ablatherm® HIFU treatment since 2003. So begins the story of Jo Ann and Jerry, and perhaps countless others. In the 2005 Us TOO book, the Circles of Love Collection, we met Jerry and Jo Ann along with fifteen other families and couples facing prostate cancer. While acknowledging the challenges of the patient, these real-life inspiring stories focused on the invisible patients: the companions, spouse and family members of men with prostate cancer. Their stories provide the reader countless opportunities for reflection and discussion.

In mid-February 2006, Us TOO will release the Circles of Love Collection Discussion Guide. This tool is designed for use with the Circles of Love book and Care Kit to further bring those remarkable stories to life. Whether you use the discussion guide as part of a chapter meeting or while sitting at the kitchen table, each section provides compelling questions to consider and discuss, along with updates from many of those featured in the Circles of Love Collection. In addition, the discussion guide features absolutely everything needed to host a Companions and
PCa-Healthy Cookbook, Calendar Raise Awareness As Well As Funds for Us TOO

Twelve retirement community friends take it all off for a good cause. The calendar features nude-but-strategically-covered mature women in a light-hearted manner. Order your "Blue Ribbon Girls for Prostate Cancer" 2006 calendar today!

$15 each, shipping and handling included. Checks only please (make out to "Blue Ribbon for Prostate Cancer"). PLEASE WRITE Us TOO IN THE MEMO SECTION OF THE CHECK so a portion of your purchase can be directed to Us TOO International.

Mail your check, along with your name and complete mailing address to:
Joyce MacDonald
15 Summit Crescent
New Hamburg, Ontario, Canada, N3A 2G3
Questions? Email blueribbongirls@aol.com

John Dodson is a gourmet chef, and a prostate cancer survivor. Soon after his diagnosis in 1999, he joined a support group - the Prostate Cancer Support Group of Greater Kingsport, Tenn. (affiliated with Us TOO International) - and began learning about the importance of healthy diet for prostate health from Dr. Charles E. “Snuffy” Meyers.

He shares his love of cuisine in the form of a cookbook titled Blue Ribbon Recipes for Prostate Health - a collection of 170 of his favorite recipes adapted to promote prostate health. The cookbook includes recipes for appetizers & beverages, soups & salads, vegetables & side dishes, main dishes, breads & rolls, desserts, cookies & candy, and “This & That” miscellaneous items, all for only $15.50 each, shipping and handling included.

Checks or money orders only please (make out to "Prostate Cancer Support Group"). All proceeds benefit prostate cancer support group services. PLEASE WRITE Us TOO IN THE MEMO SECTION OF THE CHECK so a portion of your purchase can be directed to Us TOO International.

Mail your check, along with your name and complete mailing address to:
Prostate Cancer Support Group
Attn: John Dodson
1252 Catawba Street
Kingsport, TN 37660
Questions? Call 423-245-3234 or Email Kathryn_W_Visneski@wellmont.org

John Dodson - Gourmet chef and prostate cancer survivor

More information about both items can be found at:
http://www.ustoo.org/ProductInfo_NoPayPal.asp
US TOO FEATURED RESOURCES
To order, visit <www.ustoo.org>

1) NEW! *The Circles of Love Care Kit* – $24.99 includes S+H
Our new care kit is an excellent resource collection for friends and loved ones of those facing the battle against prostate cancer. Our care kit includes:

- *The Circles of Love Collection: Stories of Companions and Families Facing Prostate Cancer* This new book, an Us TOO original publication, is a compilation of interviews with friends and loved ones of prostate cancer patients. These supportive and inspirational stories are meant to help others who are facing similar challenges. Also available separately for $17.00 includes S+H.

- *Circles of Love Music CD* – This original collection of upbeat and inspirational songs was written to celebrate the love and support between the patient and his companions and family members. Contributing artists include Soozie Tyrell of the E Street Band, Alan Glass (who has written hits for Aretha Franklin, Earth, Wind and Fire, Kenny G and others), Jerry Peters (who has written for Luther Vandross and others), country artist Deborah Allen, and folk artist Kat Eggleston. 12 songs including pop, R&B, soul, country, folk and dance. Also available separately for $15.00 includes S+H.

- *Intimacy with Impotence: The couples guide to better sex after prostate disease* – This book, authored by Ralph and Barbara Alterowitz, is written for couples who have survived prostate cancer and whose normal sexual function has been disrupted. The authors bring a unique and personal perspective to the topics as they too live this experience. 220 pages.

- *What You Need to Know About Prostate Cancer* – from NIH and NCI
- *“Life after Cancer Treatment” Resource and Referral Guide* – excerpt from NCI

2) NEW! Prostate Cancer Car Magnets “Know Your PSA” – $5.00 – includes S+H

3) *STRIVE Initiative Wristbands* – $1.00 each plus S+H

4) *HotSheet Subscriptions* – $35 for 12 issues
HotSheets are distributed FREE at all Us TOO Support Group Chapter meetings, and on www.ustoo.org. But what if you are unable to regularly attend chapter meetings, or don’t have access to the Internet? Don’t miss an issue—we can deliver it right to your home or office!

5) “*What You Need To Know For Better Bone Health*” – FREE Us TOO brochure

6) 100 Questions & Answers About Prostate Cancer – $14.95 includes S+H
By Pamela Ellsworth, MD, John Heaney, MD, Cliff Gill

7) Prostate Cancer Resource Kit – $18.95 includes S+H
Included in this handy boxed kit:
- *A Primer on Prostate Cancer* - by Dr. Stephen Strum and Donna Pogliano
- *Know Your Options* – from Us TOO and the National Cancer Institute (NCI)
- *Prostate Cancer Treatment Guidelines for Patients* – from National Comprehensive Cancer Network (NCCN) and the American Cancer Society
- *What You Should Know About Prostate Cancer* - from Prostate Cancer Research Institute (PCRI)
- *Prostate Cancer Resource Guide* - from the American Foundation for Urologic Disease (AFUD)
- *Us TOO / Phoenix 5 CD-ROM* - developed by Robert Young

8) Understanding Prostate Cancer: A Patient's Resource Kit – $7.50 includes S+H
Included in this handy boxed kit:
- *Humanizing Prostate Cancer: A Physician-Patient Perspective* by Roger E. Schultz, MD (Physician), and Alex W. Oliver (Patient)
- *Living With Prostate Cancer* – booklet
- *Know Your Options* – from Us TOO and the National Cancer Institute (NCI)
- *Living With Advanced Prostate Cancer video* - patient testimonials on Viadur


10) Us TOO Prostate Cancer *NEWS You Can Use* – FREE e-News

Proceeds from all items benefit Us TOO’s FREE programs, support services and educational materials for prostate cancer patients and their families
Circles of Love
(Continued from page 5)

Families discussion group session.

Watch the Us TOO website <www.ustoo.org> and other Us TOO news publications for information about a FREE live, nationwide, interactive conference call to kick off the release of the Discussion Guide. This call will take place in mid-February and will provide an opportunity to share ideas and answer your questions about supporting those who create a circle of love around prostate cancer patients.

To learn more about the Circles of Love Discussion Guide or any of the Us TOO companion and family related resources, contact Elizabeth at Elizabeth@ustoo.org. (The Circles of Love Care Kit and all its individual components are available for purchase at www.ustoo.org or by calling the Us TOO Offices at 800-808-7866).

PSA Velocity Test Can Be Skewed by Lifestyle Factors: Study

A prostate cancer test that measures changes in prostate-specific antigen (PSA) over time is sensitive to lifestyle and demographic factors that can skew the results, a new study found.

The multiple screenings—known as "the PSA velocity" test—to assess PSA level rate changes, differ from the traditional once-a-year PSA test. "Unlike PSA, which is a pretty good test if it's used appropriately, PSA velocity has not been examined with the same degree of scrutiny, and the velocity appears to be affected more by lifestyle variables," said study co-author Dr. Ian M. Thompson, of the department of urology at the University of Texas Health Science Center.

He noted that non-cancer-related factors—such as prostate infections, benign prostate enlargement, medications and age—can sometimes contribute to elevated PSA.

The PSA velocity test, a multiple test alternative to the traditional yearly snapshot reading, has been touted by some experts as one potential answer to accuracy concerns.

Looking at both traditional and velocity PSA testing, Thompson and his colleagues assessed the influence that outside factors have on accuracy by reviewing PSA readings among 3,341 healthy, primarily white men over the age of 55. Seven years of digital rectal exam and PSA testing, followed by biopsies, had revealed that none of the men had prostate cancer.

Demographic information included race, age, diet, smoking habits, supplement use, height, weight, body mass index and physical activity habits.

PSA velocity numbers were found to be 38 percent higher among black men than white men, but lower among men who routinely took high-dose calcium supplements. Velocity numbers also came in 33 percent lower among smokers than non-smokers.

Thompson and his colleagues concluded that once-yearly PSA tests—while affected by external factors—would probably not be affected to the point of being unreliable.

Dr. Durado Brooks, director of prostate and colorectal cancers at the American Cancer Society, described the study findings as interesting, but not a harbinger of imminent change regarding the way PSA tests of either kind are administered or read.

"It does give physicians a little information as to how to make assessments in terms of PSA velocity," said Brooks. "But I think the impact on patients is very limited."

HealthDay News, 12 December 2005

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