



Press Release

FDA Approves PROVENGE(R) for the Treatment of Men with Advanced Prostate Cancer

-- First FDA-Approved Autologous Cellular Immunotherapy Prolongs Survival --
Company to Host Conference Call Today at 2:30 pm ET / 11:30 am PT--

SEATTLE, April 29, 2010 /PRNewswire via COMTEX/ --Dendreon Corporation (Nasdaq: DNDN) today announced that the U.S. Food and Drug Administration (FDA) has approved PROVENGE(R) (sipuleucel-T), an autologous cellular immunotherapy for the treatment of asymptomatic or minimally symptomatic metastatic, castrate-resistant (hormone-refractory) prostate cancer (CRPC). PROVENGE is designed to induce an immune response against prostatic acid phosphatase (PAP), an antigen expressed in most prostate cancers, and is the first in a new therapeutic class known as autologous cellular immunotherapies.

"The FDA approval of PROVENGE is a testament to the courage of the patients and researchers who participated in our studies and is the culmination of nearly 15 years of research and development by our dedicated employees," said Mitchell H. Gold, M.D., president and chief executive officer of Dendreon. "The approval of PROVENGE is a significant step towards realizing our mission of transforming the lives of patients with cancer, and it also marks Dendreon's transformation into a commercial enterprise, ready to support the successful launch of the first personalized treatment for cancer."

Dendreon intends to make PROVENGE available through approximately 50 centers, all of which were approved PROVENGE clinical trial sites, and expects to increase capacity over the next year. The increased capacity will be a result of the anticipated licensure of its expanded New Jersey, Atlanta, Georgia and Orange County, Calif. facilities in mid-2011.

"The approval of PROVENGE, the first autologous cellular immunotherapy, represents a significant scientific and clinical advancement for the treatment of prostate cancer," said Philip Kantoff, M.D., Director of the Lank Center for Genitourinary Oncology, Chief of the Division of Solid Tumor Oncology, and Chief Clinical Research Officer at Dana-Farber Cancer Institute, Professor of Medicine at Harvard Medical School. "Cancer immunotherapies that use the patient's own immune system will likely create an entirely new treatment paradigm for patients with cancer."

Clinical Trial Results Supporting FDA Approval

Three Phase 3 studies involving 737 patients were submitted to FDA to support licensure. The pivotal study was the Phase 3 IMPACT (IMmunotherapy for Prostate AdenoCarcinoma Treatment) trial (D9902B), a 512-patient, multi-center, randomized, double blind, placebo-controlled study that evaluated men with asymptomatic or minimally symptomatic, metastatic CRPC. PROVENGE extended median survival beyond two-years, demonstrating a median improvement of 4.1 months compared to the control group (25.8 months versus 21.7 months). Overall, PROVENGE reduced the risk of death by 22.5 percent compared to the control group (HR=0.775). Results from the similarly designed Study D9901 in asymptomatic metastatic CRPC also demonstrated a survival advantage of similar clinical magnitude as the IMPACT study.

"The approval of PROVENGE represents a significant advancement in the care of men with advanced prostate cancer. PROVENGE offers a new choice in the front line treatment for these men who - until today - had few appealing treatment options," said David Penson, M.D., Professor of Urologic Surgery at Vanderbilt University Medical Center.

PROVENGE Safety

PROVENGE is intended solely for autologous use and is not routinely tested for transmissible infectious diseases.

The safety evaluation of PROVENGE was based on 601 prostate cancer patients in four randomized clinical trials who underwent at least one leukapheresis procedure. The most common adverse events (incidence greater-than or equal to 15%) are chills, fatigue, fever, back pain, nausea, joint ache, and headache. Serious adverse events reported in the PROVENGE group include acute infusion reactions (occurring within 1 day of infusion) and cerebrovascular events. In controlled clinical trials, severe (Grade 3) acute infusion reactions were reported in 3.5% of patients in the PROVENGE group. Reactions included chills, fever, fatigue, asthenia, dyspnea, hypoxia, bronchospasm, dizziness, headache, hypertension, muscle ache, nausea, and vomiting. No Grade 4 or 5 acute infusion reactions were reported in patients in the PROVENGE group.

To fulfill a post marketing requirement and as a part of the company's ongoing commitment to patients, Dendreon will conduct a registry of approximately 1500 patients to further evaluate a small potential safety signal of cerebrovascular events. In four randomized clinical trials of PROVENGE in prostate cancer patients, cerebrovascular events were observed in 3.5% of patients in the PROVENGE arm compared with 2.6% of patients in the control arm.

About PROVENGE and Patient Resources

PROVENGE (sipuleucel-T) is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic, castrate resistant (hormone-refractory) prostate cancer. PROVENGE represents the first product in a new therapeutic class known as autologous cellular immunotherapies.

Dendreon will donate funds to an independent non-profit organization that will provide financial assistance to patients who cannot afford the co-payments associated with their prostate cancer medicines. In addition, Dendreon's dedicated call center case managers will proactively help match patients with foundations to support their financial assistance needs.

For more information, please visit <http://www.provenge.com/>.

Conference Call Information

Please be advised that Dendreon will not be hosting a first quarter financial results call.

To access the live conference call, dial 1-866-788-0546 (domestic) or 857-350-1684 (international) participant passcode: 35405823. The call also will be audio webcast and will be available from the Company's website at <http://www.dendreon.com/> under the "Investor/Webcasts and Presentations" section. There will be a slide presentation to accompany the call, which will also be available on this section of the Dendreon website. A recorded rebroadcast will be available for interested parties unable to participate in the live conference call by dialing 888-286-8010 or 617-801-6888 (international); the participant pass code is 18379189. The replay will be available from April, 29 at 9:00 p.m. ET until May 13 at 11:59 p.m. ET. In addition, the webcast will be archived for on-demand listening for 30 days at <http://www.dendreon.com/>

About Active Cellular Immunotherapy

PROVENGE is classified by the FDA as an autologous cellular immunotherapy. It is designed to be an active cellular immunotherapy. Active cellular immunotherapy is designed to stimulate a T-cell response to cancer cells. An immune response is started by a specialized class of immune system cells called antigen-presenting cells (APCs). APCs take up antigen from their surroundings and process the antigen into fragments that are then displayed on the APC surface. Once displayed, these antigens can be recognized by specific classes of immune cells called T lymphocytes (T-cells), which are activated as a result of their engagement with APCs and combat disease by seeking antigen-bearing cells directly. PROVENGE is designed to target the prostate cancer antigen prostatic acid phosphatase (PAP), an antigen that is expressed in more than 95 percent of all prostate cancers.

About Prostate Cancer

According to the American Cancer Society, prostate cancer is the most common non-skin cancer in the United States and the third most common cancer worldwide. More than two million men in the United States have prostate cancer, with an estimated 192,280 new cases and approximately 27,360 men expected to die from the disease in 2009.

About Dendreon

Dendreon Corporation is a biotechnology company targeting cancer and transforming lives through the discovery, development, commercialization and manufacturing of novel therapeutics. The Company applies its expertise in antigen identification, engineering and cell processing to produce active cellular immunotherapy product candidates designed to stimulate an immune response in a variety of tumor types. Dendreon's first autologous cellular immunotherapy product, PROVENGE(R) (sipuleucel-T), was approved by the FDA in April 2010 for the treatment of asymptomatic or minimally symptomatic metastatic, castrate-resistant (hormone-refractory) prostate cancer. Dendreon also is developing an orally-available small molecule that targets TRPM8 that could be applicable to multiple types of cancer. The Company is headquartered in Seattle, Washington and is traded on the Nasdaq Global Market under the symbol DNDN. For more information about the Company and its programs, visit <http://www.dendreon.com/>

This news release contains forward-looking statements that are subject to risks and uncertainties. Factors that could affect these forward-looking statements include, but are not limited to, developments affecting Dendreon's business and prospects, including commercialization of PROVENGE. Information on the factors and risks that could affect Dendreon's business, financial condition and results of operations are

contained in Dendreon's public disclosure filings with the U.S. Securities and Exchange Commission, which are available at www.sec.gov. Dendreon cautions investors not to place undue reliance on the forward-looking statements contained in this press release. All forward-looking statements are based on information currently available to Dendreon on the date hereof, and Dendreon undertakes no obligation to revise or update these forward-looking statements to reflect events or circumstances after the date of this press release, except as required by law.

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