Dendreon Announces Increased Capacity and Significant Reimbursement Decisions Supporting Broad Availability of PROVENGE

- FDA Approves Los Angeles Immunotherapy Manufacturing Facility, CMS Announces National Coverage Decision, and Product Specific Q-Code Effective -

SEATTLE, June 30, 2011 /PRNewswire/ -- Dendreon Corporation (Nasdaq: DNDN) today announced significant milestones that support broad availability for on-label use of PROVENGE® (sipuleucel-T), the first autologous cellular immunotherapy for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer (mCRPC).

- The U.S. Food and Drug Administration (FDA) approved the Los Angeles immunotherapy manufacturing facility on June 29, 2011. The facility includes 36 workstations, and Dendreon will bring these on in a staged approach.
- In addition, the Centers for Medicare and Medicaid Services (CMS) issued a final National Coverage Decision (NCD) for PROVENGE on June 30, 2011, requiring Medicare contractors to cover the use of PROVENGE for treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. The NCD will standardize coverage processes across the country for all Medicare patients with asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer and provides the local Medicare Administrative Contractors (MACs) specific criteria, consistent with the label, on how PROVENGE should be covered.
- PROVENGE was issued a product specific Q-code effective July 1, 2011, which allows for electronic submission of claims and is expected to accelerate time to payment for physicians.
- As part of this expanded access, Dendreon supports programs to provide comprehensive assistance for eligible patients seeking access to treatment with PROVENGE, including through grants to independent foundations and establishment of a patient assistance program for uninsured patients. Dendreon provides grants to independently run foundations providing qualifying patients with financial assistance for co-pays, co-insurance, and treatment-related travel costs.

“These significant achievements support broad access to PROVENGE, the foundation of care for men with asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer,” said Mitchell H. Gold, M.D., president and chief executive officer of Dendreon. “The increased capacity and positive National Coverage Decision by CMS in conjunction with the patient assistance programs will ensure patients who may benefit from treatment with PROVENGE have increased access to it.”

For information about these programs, please visit www.provenge.com or call 1-877-336-3736.

PROVENGE Indication and Safety

PROVENGE was approved by the U.S. Food and Drug Administration in April 2010 as the first autologous cellular immunotherapy for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

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%) reported in patients in the PROVENGE group are chills, fatigue, fever, back pain, nausea, joint ache, and headache. Serious adverse events reported in patients 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 1,500 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 group compared with 2.6% of patients in the control group.

For more information on PROVENGE, please see the full Prescribing Information at www.provenge.com or call 1-877-336-3736.
About Prostate Cancer

According to the American Cancer Society, prostate cancer is the most common non-skin cancer in men 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 240,890 new cases and approximately 33,720 men expected to die from the disease in 2011.

About Dendreon

Dendreon Corporation is a biotechnology company whose mission is to target cancer and transform 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 (ACI) product candidates designed to stimulate an immune response in a variety of tumor types. Dendreon's first product, PROVENGE® (sipuleucel-T), was approved by the U.S. Food and Drug Administration (FDA) in April 2010 for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. Dendreon is exploring the application of additional ACI product candidates and small molecules for the potential treatment of a variety of cancers. 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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