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FDA Approves Dendreon's Los Angeles Cancer Immunotherapy Manufacturing Facility

-FDA Approval of 36 Workstations Further Supports National Availability of First-in-Class Prostate Cancer Immunotherapy PROVENGE-

SEATTLE, June 29, 2011 /PRNewswire/ -- Dendreon Corporation (Nasdaq: DNDN) today announced that the U.S. Food and Drug Administration (FDA) approved its Los Angeles cancer immunotherapy manufacturing facility, allowing the company to continue to increase the availability of PROVENGE® (sipuleucel-T) across the U.S. to help meet the needs of patients with asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

The Los Angeles facility includes 36 workstations, and Dendreon will bring these new workstations online in a staged approach. With this FDA approval and the fully approved New Jersey facility, Dendreon now has total of 84 workstations available to manufacture PROVENGE. Dendreon expects to continue to provide additional capacity through the anticipated licensure mid-year of one other manufacturing facility in the United States. In April, Dendreon filed a post-approval supplement for its third facility in Atlanta, for which there is an FDA action date of August 28, 2011.

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 of drugs known as autologous cellular immunotherapies.

"As the foundation of care, PROVENGE is an important treatment option for men with metastatic castrate resistant prostate cancer," said Mitchell H. Gold, M.D., president and chief executive officer of Dendreon. "The FDA approval of the Los Angeles facility will enhance our ability to provide PROVENGE to the many patients across the country who may benefit from it."

In anticipation of the availability of the additional workstations, Dendreon expects to have approximately 225 active infusing sites by the end of the second quarter and approximately 500 by the end of 2011.

PROVENGE was approved based on three Phase 3 studies, including the pivotal, 512-patient Phase 3 IMPACT study, which showed that PROVENGE demonstrated a statistically significant improvement in overall survival compared to control in men with asymptomatic or minimally symptomatic metastatic castration resistant prostate cancer (CRPC). That trial showed PROVENGE extended median survival by 4.1 months compared to control. Overall, PROVENGE reduced the risk of death by 22.5 percent compared to the control group (HR=0.775). Results from the similarly designed Phase 3 Study D9901 in asymptomatic metastatic CRPC also demonstrated a survival advantage of similar clinical magnitude as the IMPACT study.

PROVENGE Indication and Safety

PROVENGE is an autologous cellular immunotherapy indicated 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. 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 group compared with 2.6% of patients in the control group.

For more information on PROVENGE, please see the full prescribing information 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 and commercialization 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. Dendreon's first autologous cellular immunotherapy product, PROVENGE[®] (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 is also 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 has manufacturing facilities in New Jersey, Georgia and California. Dendreon 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/>.

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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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