



February 13, 2013

New PROVENGE® (sipuleucel-T) Data to Be Presented at 2013 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium

-- *Two studies examine potential for PROVENGE in combination or sequenced with two approved advanced prostate cancer therapies*

-- *Additional retrospective study data suggest that relative to placebo, PROVENGE may delay time to first opioid use for pain in patients with advanced prostate cancer*

-- *Preliminary data on NeuACT study for high-risk urothelial carcinoma show high frequency of HER2 expression at primary tumor and lymph node samples*

BRIDGEWATER, N.J.--(BUSINESS WIRE)-- **February 13, 2013**--Dendreon Corporation (NASDAQ: [DNDN](#)) today announced that results from several ongoing or completed studies investigating the utility of PROVENGE® (sipuleucel-T) in the treatment of advanced prostate cancer, including studies that may lead to new treatment approaches, as well as the investigational immunotherapy DN24-02 in patients with surgically-resected urothelial cancer, will be presented at the 2013 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium in Orlando, Florida, from February 14-16, 2013.

"This year's ASCO GU meeting is important for Dendreon because of the wide range of studies being presented that help us better understand PROVENGE," said Mark Frohlich, M.D., executive vice president of research and development and chief medical officer at Dendreon. "The studies that inform us about the potential use of PROVENGE in combination or sequenced with other advanced prostate cancer treatments are encouraging, and we look forward to additional data from these studies."

Data presented include and can be accessed via the following links:

- [Abstract #34: Randomized Phase II Trial Evaluating the Optimal Sequencing of Sipuleucel-T and Androgen Deprivation Therapy \(ADT\) in Patients with Biochemically-Recurrent Prostate Cancer \(BRPC\)](#): A Phase II sequencing study evaluating PROVENGE followed by ADT or ADT followed by PROVENGE in men with biochemically-recurrent prostate cancer showed a prime-boost immune response effect based on antigen presenting cell activation patterns, and an analysis of serum samples indicated that there were no differences between the arms in cellular or humoral immune responses. Adverse events for each treatment were consistent with what was seen in pivotal trials.
- [Abstract #114: A Randomized Phase II, Open-Label Study of Sipuleucel-T with Concurrent or Sequential Abiraterone Acetate \(AA\) in Metastatic Castrate-Resistant Prostate Cancer \(mCRPC\)](#): A Phase II study evaluating concurrent or sequential therapy with AA plus prednisone (P) in men with metastatic castrate resistant prostate cancer demonstrated no significant differences in median cumulative CD54 upregulation (31.6 vs. 36.6), or the measure of antigen presenting cell activation, and CD54+ count (1.9 vs. 2.1×10^9) between the two arms, suggesting that PROVENGE can be manufactured during treatment with AA + P therapy. Adverse events for each treatment were consistent with what was seen in pivotal trials.
- [Abstract #74: Sipuleucel-T Appears to Delay Time to First Use of Opioid Analgesics \(TFOA\) in Patients with Asymptomatic or Minimally Symptomatic Metastatic Castration Resistant Prostate Cancer \(mCRPC\) on the IMPACT Trial](#): A retrospective analysis of a subset of the IMPACT trial demonstrated that relative to placebo, treatment with PROVENGE appeared to delay the first use of opioid analgesics for pain associated with advanced prostate cancer. Opioid therapy is currently recommended by the World Health Organization (WHO) for moderate to severe pain associated with cancer. In patients with advanced cancer, pain is described as moderate to severe in approximately 40-50 percent and very severe or excruciating in 25-30 percent of cases.¹
- [Abstract #292: HER2 Expression in Patients with Surgically Resected Urothelial Cancer at High Risk of Recurrence Screened for the Phase II Randomized, Open-Label Trial of DN24-02, an Autologous Cellular Immunotherapy Targeting HER2](#): In the NeuACT study, Dendreon's investigational DN24-02 is being studied in urothelial carcinoma. Preliminary data presented show a high frequency (> 80 percent) of HER2 expression score of > 1+ found in primary tumor and lymph node samples of patients with high-risk urothelial carcinoma, as is consistent with previously published data.

"These preliminary PROVENGE data are promising for the treatment of metastatic castrate resistant prostate cancer," said Eric Small, M.D., Chief of the Division of Hematology and Oncology, and Deputy Director, UCSF Helen Diller Family Comprehensive

Cancer Center. "The medical community is particularly excited about the studies investigating the potential for treatment with PROVENGE and other currently approved treatments for advanced prostate cancer, which may provide us with new therapeutic approaches to help men fight this disease in the future."

Additional Dendreon abstracts accepted for presentation at the meeting can be accessed via the following links:

- [Abstract #148: Immune Response with Sipuleucel-T in Patients with Metastatic Castrate-Resistant Prostate Cancer \(mCRPC\): Phase II PROACT Study](#)
- [Abstract #147: P10-1 Open Label, Multicenter Study of Sipuleucel-T in Metastatic Castrate-Resistant Prostate Cancer \(mCRPC\) Patients Previously Treated with Sipuleucel-T: Evaluation of Antigen Presenting Cell \(APC\) Activation](#)
- [Abstract #131: Real-World Experience with Sipuleucel-T in Metastatic Castration-Resistant Prostate Cancer \(mCRPC\) Patients > 80 Years Old: Data from PROCEED](#)
- [Abstract #30: Real-World Experience with Sipuleucel-T in Patients with Metastatic Castration-Resistant Prostate Cancer \(mCRPC\) Who Received Prior Docetaxel \(D\): Data from PROCEED](#)

About PROVENGE

Indication and Important Safety Information

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 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 the FDA approved full prescribing information, please visit <http://www.provenge.com>.

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 FDA in April 2010. 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>.

Statements in this press release that are not strictly historical in nature constitute "forward-looking statements." Such statements include, but are not limited to, statements regarding the expected benefits of the restructuring, the timing and elements of the restructuring, the timing and form of related charges, the expected annual operating expense reduction, expectations and beliefs regarding Dendreon's profitability and Dendreon's ability to achieve improved performance as a result of the restructuring, expectations regarding regulatory approval of PROVENGE[®] in Europe, expectations regarding the presentation of clinical data, developments affecting Dendreon's U.S. and global business and prospects and potential revenue and earnings from product sales, expectations regarding market size and market opportunity, and progress generally on commercialization efforts for PROVENGE. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause Dendreon's actual results to be materially different from historical results or from any results expressed or implied by such forward-looking statements. These factors include, but are not limited to, our inability to achieve and sustain commercial success for PROVENGE; the identification of efficacy, safety or other issues with PROVENGE; a slower than anticipated adoption by treating physicians of PROVENGE for the treatment of patients with advanced prostate cancer due to

competing therapies, perceived difficulties in the treatment process, delays in obtaining reimbursement or for other reasons; any promotional limitations imposed by the FDA on our ability to commercialize and market PROVENGE; unexpected difficulties and costs associated with the rapid expansion of our operations to support the commercial launch of PROVENGE; and other factors discussed in the "Risk Factors" section of Dendreon's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012. All forward-looking statements are qualified in their entirety by this cautionary statement. Dendreon is providing this information as of the date of this press release and does not undertake any obligation to update any forward-looking statements contained in this release as a result of new information, future events or otherwise.

1. Coyle N, Adelhardt J, Foley KM, Portenoy RK. Character of terminal illness in the advanced cancer patient: pain and other symptoms during the last four weeks of life. *J Pain Symptom Manage* 1990;5:83—93.

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