



May 21, 2012

Dendreon Announces Data Presentation at the 2012 American Urological Association Annual Meeting

SEATTLE--(BUSINESS WIRE)-- **May 21, 2012**—Dendreon Corporation (NASDAQ: [DNDN](#)) today announced the following PROVENGE® (sipuleucel-T) data will be presented at the American Urological Association (AUA) Annual Meeting taking place May 19 — 23, 2012 in Atlanta, Georgia.

- "Sipuleucel-T in African Americans: A Subgroup Analysis of Three Phase 3 Trials of Sipuleucel-T in Metastatic Castrate Resistant Prostate Cancer," abstract #953. Moderated Poster Session, Prostate Cancer: Advanced III from 10:30 a.m. to 12:30 p.m. ET on Monday, May 21, 2012.
- "Estimating the Overall Survival Benefit of Sipuleucel-T in the IMPACT Trial Accounting for Crossover Treatment in Control Subjects with Autologous Immunotherapy Generated From Cryopreserved Cells," abstract #683. Oral Presentation, Prostate Cancer: Advanced 1 Podium from 3:30 to 5:30 p.m. ET on Sunday, May 20, 2012.

"These data continue to support the overall survival benefit of PROVENGE, an important treatment option for men with asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer," said Mark Frohlich, MD, executive vice president and chief medical officer. "As shown in Phase 3 clinical trials, PROVENGE demonstrated an overall survival benefit and represents an important treatment option for men with advanced prostate cancer."

Abstract #953: Sipuleucel-T in African Americans: A Subgroup Analysis of Three Phase 3 Trials of Sipuleucel-T in Metastatic Castrate Resistant Prostate Cancer

This exploratory analysis evaluated the survival benefit associated with PROVENGE in the African American men who participated in the three PROVENGE Phase 3 studies, including the IMPACT trial. Among 737 patients with metastatic castrate resistant prostate cancer, 488 were randomized to receive PROVENGE (African American, 33; Caucasian, 437; other races, 18) and 249 were randomized to the control arm (African American, 10; Caucasian, 229; other races, 10). Cox proportional hazards regression analysis was used to assess the treatment effect on overall survival in all randomized patients and the African American subpopulation.

The results of the African American subgroup suggested a positive treatment effect (HR=0.288 [95% CI: 0.125, 0.662]; P = 0.003). The exploratory analysis showed that African American men treated with PROVENGE had median overall survival benefit of 45.3 months versus 14.6 months in the control arm, a median survival difference of 30.7 months.

While no definitive conclusions can be drawn given the limited sample size, the results suggest that African American patients with metastatic castrate resistant prostate cancer benefit from treatment with PROVENGE and provide support for further investigation of this hypothesis. There were no statistically significant differences between race groups. Baseline factors for the African American population relative to the overall population included more exposure to prior chemotherapy, and lower age, baseline hemoglobin, ECOG status and bisphosphonate use. Adverse events for the African American subgroup were comparable to the overall study population.

"African American men are at the highest risk for prostate cancer in the United States and suffer a death rate 2.4 times higher when compared to Caucasian men and men of other ethnic groups," said Thomas A. Farrington, president and founder, Prostate Health Education Network, Inc. "As a member of this community and a leader of an organization focused on eliminating health disparity, I welcome the data presented today. There is a great need for new treatment options for Black men."

"The exploratory analysis suggests African American men with metastatic castrate resistant prostate cancer benefit from treatment with PROVENGE," said David McLeod, MD, Center for Prostate Disease Research, Uniformed Services University, Bethesda, Maryland. "These data support further evaluation of the survival benefits associated with PROVENGE in appropriate African American advanced prostate cancer patients."

Abstract #683: Estimating the Overall Survival Benefit of Sipuleucel-T in the IMPACT Trial Accounting for Crossover Treatment in Control Subjects with Autologous Immunotherapy Generated From Cryopreserved Cells

The Phase 3 IMPACT trial included a crossover design that allowed patients who were randomized to the control arm and experienced disease progression the opportunity to participate in an open label Phase 2 protocol to receive APC8015F, an

investigational autologous cellular immunotherapy made from cells that were cryopreserved at the time the control was manufactured. As a result, 109 out of the 171 control patients (64%) received APC8015F.

In this exploratory analysis, researchers used a rank-preserving structural failure time (RPSFT) model, to quantify how treatment with APC8015F might have impacted the overall survival of the Phase 3 IMPACT trial by adjusting for the positive treatment effect of APC8015F in the control arm. The previously published intent to treat analysis, which is described in the Food and Drug Administration approved prescribing information for PROVENGE, did not account for cross-over and demonstrated a 4.1 month median survival benefit (HR=0.775, 95% CI: 0.614, 0.979). Using the RPSFT model, and assuming that APC8015F was equally effective as PROVENGE, the median overall survival benefit of PROVENGE in the Phase 3 IMPACT trial was estimated to be 7.8 months, had there been no cross-over to APC8015F (HR=0.60, 95% CI: 0.41, 0.95).

"This exploratory analysis provides important insight into how the cross-over design of the IMPACT trial may have affected the overall survival findings," said Leonard Gomella, MD, Kimmel Cancer Center of Thomas Jefferson University. "These data support the use of PROVENGE as a foundation of care for the treatment of metastatic castrate resistant prostate cancer."

About the IMPACT Trial

IMPACT (IMmunotherapy for Prostate AdenoCarcinoma Treatment) is a 512-patient, multi-center, randomized, double-blind, controlled study evaluating men with asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. The primary endpoint was overall survival.

Primary results from the IMPACT study found PROVENGE extended median survival by 4.1 months compared to control (25.8 months vs. 21.7 months) and reduced the risk of death by 22.5 percent compared to control. Control used in the trial was non-activated autologous peripheral blood mononuclear cells. The survival benefit associated with PROVENGE was observed consistently across multiple patient subgroups, including those with prognostic factors known to be adversely correlated with overall survival, such as PSA, LDH, alkaline phosphatase, number of bone [metastasis](#), Gleason score, performance status, and presence of pain.

Adverse events more commonly reported in the PROVENGE arm of this study included chills, fever, headache, influenza-like illness, muscle aches, hypertension and groin pain.

PROVENGE[®] Indication and Important Safety Information

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 at <http://www.provenge.com> or call 1-877-336-3736.

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>.

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 progress on the commercialization efforts for 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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