May 20, 2014

Treatment with PROVENGE® (sipuleucel-T) Induces Antigen Spread Associated with Overall Survival Benefits In Advanced Prostate Cancer

Data from ProACT, IMPACT and PROCEED to be Presented at the 2014 American Urological Association (AUA) Annual Meeting

SEATTLE--(BUSINESS WIRE)-- May 20, 2014-Dendreon Corporation (NASDAQ: DNDN) today announced the presentation of data from the ProACT and IMPACT studies suggesting that PROVENGE® (sipuleucel-T) elicits an immune response associated with an overall survival benefit. Also being presented are data from the PROCEED registry suggesting similar treatment patterns for urologists and oncologists in PROVENGE-treated patients with metastatic castration-resistant prostate cancer (mCRPC). The ProACT and IMPACT data will be reported in a podium presentation and the PROCEED data will be included in a general poster session during the 2014 American Urological Association (AUA) Annual Meeting from May 16-21, 2014 in Orlando, Florida.

"These data further elucidate the mechanism of PROVENGE in the treatment of mCRPC and the important role immunotherapy plays in the prescribing practices of urologists and oncologists, which may improve outcomes for patients," said Andrew S. Sandler, M.D., executive vice president and chief medical officer at Dendreon. "The elevated immune response against prostate-specific antigen (PSA) in the ProACT and IMPACT studies is correlated with overall survival, and may point to a useful biomarker of treatment benefit."

Clinical presentations featuring PROVENGE studies at the annual scientific urology meeting include:

- Abstract PD27-04: Simon Hall, M.D., associate professor of urology at Mt. Sinai Hospital, will present "Sipuleucel-T-Induced Antigen Spread: Immune Response to Prostate-Specific Antigen Correlates with Improved Overall Survival:" Data from the Phase III IMPACT and Phase II ProACT studies show evidence that antigen spread may occur after PROVENGE treatment, indicating the immune response evolves over time to target multiple prostate antigens. These data may help identify biomarkers of clinical outcome after treatment with PROVENGE. May 20, 8:00 AM - 10:00 AM ET, Prostate Cancer: Advanced I (Podium Presentation, Room W304E)

- Abstract MP70-20: Matthew R. Cooperberg, M.D., M.P.H, associate professor of urology at University of California, San Francisco, will present a poster titled "Treatment Practice Patterns in Metastatic Castration-Resistant Prostate Cancer (mCRPC) Patients Prior to Receiving Sipuleucel-T: Data from PROCEED:" A subgroup analysis from the ongoing Phase IV registry of mCRPC patients suggest treatment patterns between urologists and oncologists are similar, helping to better understand prescribing trends prior to and following use of PROVENGE. May 20, 10:30 AM - 12:30 PM ET, Prostate Cancer: Advanced II (Moderated Poster Session, Room W307)

"The evolution of immunotherapy treatment continues to be a focus for the future of urology research, as evidenced in the PROVENGE data presented at AUA," said Simon Hall, M.D., associate professor of urology at Mt. Sinai Hospital. "The biomarker potential of the anti-PSA immune response suggested in the IMPACT and ProACT data is exciting as it continues to reinforce the positive impact immunotherapies and PROVENGE may have on patients with mCRPC."

Important Safety Information for PROVENGE

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 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 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 U.S. Food and Drug Administration (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 recent and prior restructurings, the timing and elements of the restructurings, the timing and form of related charges, the expected annual operating expense reductions, expectations and beliefs regarding Dendreon’s financial position, profitability and Dendreon’s ability to break even and achieve improved performance as a result of the restructurings, statements regarding sequencing studies, statements regarding studies to advance understanding of immunotherapy and the treatment of advanced prostate cancer, statements regarding biomarkers, expectations about automation or the early detection study, expectations about advancing our pipeline, expectations regarding reductions of cost of goods sold, expectations regarding reimbursement approvals of PROVENGE® in Europe or Dendreon’s ability to launch and commercialize PROVENGE in Europe, expectations regarding the presentation of clinical data, developments affecting Dendreon’s U.S. and global business and prospects, beliefs and expectations regarding potential revenue and earnings from product sales, including beliefs regarding Dendreon’s ability to grow sales, expectations regarding market size, target market, and market opportunity, beliefs regarding the impact of our direct to consumer advertising, expectations with respect to our sales force execution and effectiveness, progress generally on commercialization efforts for PROVENGE, and expectations about clinical trial enrollments. 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 for a variety of reasons, including competing therapies, instability in our sales force, the risk that we cannot replace vacant sales positions on a prompt basis, perceived difficulties in the treatment process, delays in obtaining reimbursement or for other reasons; any promotional limitations imposed by the FDA or the EU on our ability to commercialize and market PROVENGE; unexpected difficulties and costs associated with the rapid expansion of our commercial operations to support the commercial launch of PROVENGE; the impact of competing therapies on sales of PROVENGE, the failure to achieve reimbursement approvals in Europe, manufacturing or quality difficulties, the dilution or other effects resulting from capital raising or debt restructuring transactions, disruptions or delays and other factors discussed in the “Risk Factors” section of Dendreon’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2014. 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.

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Source: Dendreon Corporation

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