September 17, 2013

Dendreon Announces Marketing Authorization for PROVENGE® in the European Union

SEATTLE--(BUSINESS WIRE)-- September 17, 2013 — Dendreon Corporation (Nasdaq: DNDN) today announced that the European Commission (EC) has granted marketing authorization for PROVENGE® (autologous peripheral blood mononuclear cells activated with PAP-GM-CSF or sipuleucel-T) dispersion for infusion in the European Union (EU) for the treatment of asymptomatic or minimally symptomatic metastatic (non-visceral) castrate resistant prostate cancer in male adults in whom chemotherapy is not yet clinically indicated. This final decision by the EC follows recent positive opinions from both the European Medicines Agency (EMA) Committee for Advanced Therapy (CAT) and the Committee for Medicinal Products for Human Use (CHMP) recommending that PROVENGE be granted marketing authorization in the EU.

The marketing authorization provides approval for the commercialization of PROVENGE in all 28 countries of the EU as well as Norway, Iceland and Liechtenstein.

John H. Johnson, chairman, president and chief executive officer of Dendreon said, "The marketing authorization of PROVENGE in the EU represents an important achievement for Dendreon. As the first personalized immunotherapy approved for the treatment of mCRPC in Europe, PROVENGE may help extend the lives of appropriate prostate cancer patients."

"With sipuleucel-T, we have the potential to create a new treatment paradigm in advanced prostate cancer, with the integration of this novel therapy to harness a patient's own immune system to fight their cancer," said Prof. Karim Fizazi, M.D., Ph.D., Head of the Department of Cancer Medicine, The Institut Gustave Roussy, Villejuif, and Full Professor in Oncology, the University of Paris, France.

The European marketing authorization for PROVENGE was granted based upon data from three randomized, placebo-controlled, multi-center Phase III studies, which enrolled 737 patients. In the pivotal Phase III IMPACT study, an improvement in overall survival (OS) was observed, with a median survival of 4.1 months longer in patients who received PROVENGE versus those who received placebo (HR=0.775, 95%-CI 0.614, 0.979, P =0.032). Similar effects were observed in the two supportive studies.

"This milestone demonstrates the importance of providing a new therapeutic option with a differing mechanism of action than other approved treatments for appropriate prostate cancer patients in the EU," said Mark Frohlich, executive vice president of research and development and chief medical officer of Dendreon. "We continue to enroll patients in the EU open-label study, and plan to have a presence at the upcoming European Cancer Organization (ECCO) and European Society for Medical Oncology (ESMO) conferences."

Important Safety Information for PROVENGE[1]

PROVENGE is intended solely for autologous use and should under no circumstances be administered to other patients.

The safety evaluation of PROVENGE was based on data from 601 prostate cancer patients in four randomized clinical trials and post-marketing surveillance.

PROVENGE should be delayed in patients with active systemic infection until resolution and used with caution in patients with a history of embolic and thrombotic events, including cerebrovascular disease and cardiovascular disorders.

Serious adverse reactions reported include acute infusion reactions (occurring within 1 day of infusion), catheter sepsis, staphylococcal bacteremia, myocardial infarction and cerebrovascular events.

The most commonly reported adverse reactions were chills, fatigue, pyrexia (fever), nausea, arthralgia (joint ache), headache, and vomiting.

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 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 financial position, profitability and Dendreon's ability to break even and achieve improved performance as a result of the restructuring, statements regarding sequencing studies, statements regarding studies to advance understanding of immunotherapy and the treatment of advanced prostate cancer, statements regarding biomarkers, expectations about the early detection study, expectations about advancing our pipeline, expectations regarding reductions of cost of goods sold, 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 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, manufacturing difficulties, disruptions or delays and other factors discussed in the "Risk Factors" section of Dendreon's Annual Report on Form 10-Q for the quarter ended June 30, 2013. 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] PROVENGE Summary of Product Characteristics (SmPC) for the European Union

Dendreon Corporation
Corporate Communications
Lindsay Rocco, 862-596-1304
media@dendreon.com
or
Investor Relations
Nicole Soley, 206-455-2220
ir@dendreon.com

Source: Dendreon Corporation