



September 28, 2012

First Patient In Dendreon EU Open-Label Study Begins Sipuleucel-T Infusion Treatment

Sipuleucel-T Data To Be Presented At The ESMO 2012 Congress (European Society for Medical Oncology)

SEATTLE--(BUSINESS WIRE)-- September 27, 2012--Dendreon Corporation (NASDAQ:[DNDN](#)) today announced the first patient enrollment and initiation of treatment for the sipuleucel-T European Union (EU) open-label study. The open-label study is being conducted in European men with metastatic castrate-resistant prostate cancer (mCRPC) to describe product release parameters and report on safety in a European population. The study may enroll up to 45 patients in four sites across the EU. Dendreon has submitted a marketing authorization application (MAA) for sipuleucel-T which is currently under review by the European Medicines Agency (EMA). Sipuleucel-T is not approved for use outside the U.S. Sipuleucel-T is approved by the Food and Drug Administration (FDA) in the U.S. for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer. It is marketed under the name PROVENGE®.

"We are extremely pleased with the progress of this new study and that the first patient has begun his treatment," said Thomas Powles MD, MRCP, Barts Cancer Institute, St. Bartholomew's Hospital, London. "We are also excited about the potential study outcomes and look forward to a successful program with the support of our committed clinical team and dedicated patients."

In addition to the current EU open-label study, the following data presentations are taking place at the ESMO 2012 Congress in Vienna, Austria, 28 September —2 October:

- Saturday, September 29, 13:00-14:00 CEST — Abstract #939P: "Neoadjuvant Sipuleucel-T in Localized Prostate Cancer: Effects on Immune Cells within the Prostate Tumor Microenvironment." Poster presentation.
- Saturday, September 29, 13:00-14:00 CEST — Abstract #940P: "Overall Survival Benefit with Sipuleucel-T by Baseline PSA: An Exploratory Analysis from Three Phase 3 Trials." Poster presentation.
- Saturday, September 29, 13:00-14:00 CEST — Abstract #941P: "Impact of Salvage Therapy with AC8015F on the Overall Survival Benefit Achieved with Sipuleucel-T in Three Phase III Studies of Metastatic Castrate-Resistant Prostate Cancer." Poster presentation.
- Saturday, September 29, 13:00-14:00 CEST — Abstract #943P: "OpenACT: Phase II, Open-Label Study of Sipuleucel-T in Metastatic Castrate-Resistant Prostate Cancer (mCRPC)." Poster presentation.
- Saturday, September 29, 13:00-14:00 CEST — Abstract #942P: "Antigen Presenting Cell (APC) Activation in Sipuleucel-T: Is Activation Increased in Earlier Prostate Cancer Disease States?" Poster presentation.

Indication and Important Safety Information

Approved for use in the U.S. only.

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>.

Dendreon Corporation
Corporate Communications
April Falcone, 206-829-1622
media@dendreon.com

Source: Dendreon Corporation

News Provided by Acquire Media