Health Bulletin

Breakthrough In Prostate Cancer Treatment Offers Exciting, Innovative Option For Patients

(NAPSA)—Since the war on cancer was launched 40 years ago, advances in the treatment of prostate cancer have been limited. In fact, to date, only four therapies have been approved by the U.S. Food and Drug Administration (FDA) that demonstrate a survival benefit in the treatment of metastatic (advanced) prostate cancer. However, cancer experts believe that one of these drugs might just be the spark that ignites a new era in cancer therapy.

The FDA has approved a treatment called Provenge® (sipuleucel-T) for men with asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. Provenge is designed to work by stimulating the patient's own immune system to fight his cancer. Each dose of Provenge is made from the patient's own immune cells.

"For many years, men with advanced prostate cancer had few options. Now, doctors have an innovative approach to combat this disease," said Daniel George, M.D., director of GU Medical Oncology and the Prostate Clinic at Duke University Medical Center. "In clinical trials, Provenge demonstrated a significant survival benefit in this patient population with mostly transient and mild to moderate side effects. Provenge is uniquely designed to harness the body's own immune system to fight advanced prostate cancer and the treatment can be completed in approximately one month."

The FDA based its approval of Provenge in part on clinical trial data that showed Provenge significantly increased overall survival by 4.1 months and reduced the risk of death by 22.5 percent versus the control arm. The majority of side effects were mild to moderate, but some patients experienced serious infusion-related reactions (see details below). Prior to the FDA approval of Provenge, the only treatment options for this patient population included watchful waiting or chemotherapy. Physicians and patients alike are welcoming this additional treatment option.

Rollin Hill of Washington, D.C., was diagnosed with prostate cancer nearly 18 years ago. When his disease progressed and he was diagnosed with metastatic prostate cancer, he was offered Provenge as part of a clinical trial at Walter Reed Medical Center, and says he was relieved to have an additional option.

"I'm glad they've come up with a different way to treat this disease," said Mr. Hill. "Provenge was designed to train my immune system to fight cancer, and I liked the idea of using my own cells to fight this battle."

The FDA has also approved the opening of additional manufacturing facilities where Provenge is made, making the drug now broadly available to patients across the country. Additionally, Medicare and all major insurance plans cover the cost of Provenge for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. Lastly, the manufacturer of Provenge provides Provenge free of charge to eligible patients with no health insurance or who are denied coverage after all claims appeals, and also supports independent foundations that offer assistance with co-pays and co-insurance charges and assistance for treatment-related travel costs. The increased capacity, insurance coverage decisions, and Provenge patient assistance will help ensure patients who could benefit from the treatment have access to it. For more information on prostate cancer and Provenge, or to find an authorized infusion site near you, please visit www.Provenge.com.

Provenge Indication and Safety

Provenge® (sipuleucel-T) is approved by the FDA as an autologous cellular immunotherapy for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

Provenge is made from your own immune cells. Your cells will be collected at a cell collection center approximately three days before each scheduled infusion of Provenge. There can be risks associated with the cell collection process, which you should discuss with your doctor before deciding to begin treatment with Provenge.

Provenge can cause serious reactions. In controlled clinical trials for the treatment of prostate cancer, serious reactions reported in patients in the Provenge group include reactions resulting from the infusion of the drug, which occurred within one day of infusion, and strokes. Severe infusion reactions included chills, fever, fatigue, weakness, breathing problems (shortness of breath, decreased oxygen level and wheezing), dizziness, headache, high blood pressure, muscle ache, nausea and vomiting. Tell your doctor right away if you have breathing problems, chest pains, racing heart or irregular heartbeats, dizziness, nausea or vomiting after getting Provenge, because any of these may be signs of heart or lung problems.

The most common side effects reported with Provenge are chills, fatigue, fever, back pain, nausea, joint ache and headache. These are not all the possible side effects of Provenge treatment. For more information, talk with your doctor.

Tell your doctor about all your medical problems, including heart problems, lung problems or a history of stroke.

Tell your doctor right away if you get a fever over 100° F, or redness at the cell collection or infusion sites, because any of these may be signs of infection.

Tell your doctor about all the medicines you take, including prescription and nonprescription drugs, vitamins and dietary supplements.

Tell your doctor about any side effect that concerns you or does not go away.

For more information on Provenge, please see the Full Prescribing Information or call Dendreon ON Call at (877) 336-3736.