FDA approves breakthrough cancer therapy Provenge

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(AP) -- A first-of-a-kind prostate cancer treatment that uses the body's immune system to fight the disease received federal approval Thursday, offering an important alternative to more intensive treatments like chemotherapy.

Dendreon Corp.'s Provenge vaccine trains the immune system to fight tumors. It's called a "vaccine" even though it treats disease rather than prevents it.

Doctors have been trying to develop such a therapy for decades, and Provenge is the first to win approval from the Food and Drug Administration.

"The big news here is that this is the first immunotherapy to win approval, and I suspect within five to ten years immunotherapies will be a big part of cancer therapy in general," said Dr. Phil Kantoff, an oncologist at the Dana-Farber Cancer Institute who helped run the studies of Provenge.

Experimental vaccines to treat other cancers - including the deadly skin disease melanoma and an often fatal childhood tumor called neuroblastoma - are already in late-stage development.

Currently doctors treat cancer by surgically removing tumors, attacking them with chemotherapy drugs or blasting them with radiation. Provenge offers an important fourth approach by directing the body's natural

defense mechanisms against the disease.

The drug is intended to treat prostate cancer that has spread elsewhere in the body and is not responding to hormone therapy.

Medical specialists hailed the approval as an important milestone, but stressed it will serve as an addition to current practice, not a replacement.

"This is just one step in a new pathway for treating patients," said Dr. Simon Hall, chairman of urology at Mt. Sinai Hospital "We have to make them realize this isn't a cure, it's very variable."

Company studies showed that taking Provenge added four months to the lives of men with advanced prostate cancer.

That may not sound like a lot, but it is longer than the three months afforded by Taxotere, the only chemotherapy approved for men in this situation. Doctors hope for even greater benefit if they give the drug earlier in the course of the disease.

Dendreon would give no cost estimate for Provenge, but analyst estimates range from between $60,000 to $100,000.

The approval marks a remarkable turnaround for Seattle-based Dendreon, whose shares plummeted three years ago when the FDA delayed a decision on the therapy, asking for more proof of safety and effectiveness. That delay came despite an expert panel's recommendation for approval.

Dendreon shares jumped 19 percent to new highs ahead of the news, rising to an all-time high of $47.32. Trading of the stock was halted at 12:34 p.m. Eastern, 35 minutes before the FDA announced its decision.

At the time, Dendreon shares were up $5.88, or 14.8 percent, at $45.50.

The company does not have any products on the market.

Analysts expect the product to reach blockbuster sales status - over $1 billion - by 2016, as the company expands production capacity.

Each regimen of Provenge must to tailored to the immune system of the patient using a time-consuming formulation process.

Doctors collect special blood cells from each patient that help the immune system recognize cancer as a threat. The cells are mixed with a protein found on most prostate cancer cells and another substance to rev up the immune system. The resulting "vaccine" is given back to the patient as three infusions two weeks apart.

Initially, Dendreon will identify Provenge patients through the medical centers that helped test the drug. But researchers have been told the company will only be able to provide vaccines for a few patients at each site per month.

"There are going to be a lot of patients that want it and there will be limited resources as they are getting this up and running," said Dr. Deborah Bradley of Duke University School of Medicine

About 192,000 new cases of prostate cancer were diagnosed in 2009, and 27,000 men died of the disease, according to the FDA. Prostate cancer most often affects older men.

Side effects of Provenge are relatively mild, such as chills, fatigue, fever, and headache. By comparison, side effects of chemotherapy typically include hair loss, nausea, anemia and diarrhea.