Prostate cancer vaccine extends survival in study

April 28 2009, By MARILYNN MARCHIONE , AP Medical Writer

(AP) -- An experimental treatment added four months to the lives of men with advanced prostate cancer, doctors reported Tuesday in a study that tested an entirely new approach to fighting the disease.

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 this is the first to meet its goal for improving survival in late-stage testing.

"There have been a lot of false starts, but this is a real start," said Dr. Paul Schellhammer, a urologist at Eastern Virginia Medical School in Norfolk, Va., who led the study. Results were reported Tuesday at an American Urological Association conference in Chicago.

Seattle-based Dendreon paid for the study, and Schellhammer owns stock in the company. Dendreon shares fell sharply and then were halted leading up to the release of the data, falling $8.80, or 40.8 percent, to $12.75. The reason was not immediately clear.

Four months 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.

It still remains to be seen if side effects will keep Provenge from winning federal Food and Drug Administration approval. Two years ago, the FDA went against its advisers and delayed a decision, asking for more proof of safety and effectiveness.

The new study involved 521 men whose cancer had spread and wasn't responding to standard hormone treatments. Two-thirds were given Provenge, a treatment that is customized for each patient.

Doctors collect special blood cells from each patient that help the immune system recognize cancer as a threat. They 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.

The other one-third of men in the study had a dummy infusion.

Median survival was 26 months in men given Provenge and 22 months in the others. Three-year survival rates were 32 percent for the Provenge group and 23 percent for the others - a 38 percent improvement.

Strokes and other brain-related problems were no more common with Provenge - a worry raised by earlier studies. However, four men given Provenge suffered lung clots, though none were fatal. High blood pressure was twice as common with Provenge. Overall, the rate of serious side effects was the same in each group.

Improving survival "is the gold standard" for any treatment, and Provenge appears to do that, said Dr. Ira Sharlip, a urologist from the University of California in San Francisco and a spokesman for the urological association.

Dr. Otis Brawley, the American Cancer Society's chief medical officer,

said the FDA had been right to ask for more study. Seeing the new results, he said, "I would vote for approval" as long as it didn't harm men's quality of life.

One patient said it did not hurt his. Thomas Robbins, 74, of Forest City, N.C., was diagnosed in 2002 with prostate cancer that was growing despite hormone treatment.

"They wanted to give me chemo," but he feared its side effects and enrolled in the Provenge study instead. He learned afterward that he had been one of those given the vaccine.

"Did it help me? I can't 100 percent guarantee, but I think it did," he said.

Prostate cancer is the most common non-skin cancer in American men. An estimated 186,000 new cases and 28,660 deaths from it occurred last year.

On the Net:

Urology group: http://www.AUAnet.org

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