

Study finds possible heart risk with prostate drug

March 31 2010, By MARILYNN MARCHIONE , AP Medical Writer

(AP) -- Full results of a big study testing a drug for preventing prostate cancer show a higher risk of heart failure, a surprise finding that could dampen enthusiasm for expanding its use.

On Monday, [GlaxoSmithKline](#) PLC asked the federal [Food and Drug Administration](#) to approve its drug Avodart as a cancer preventive for men at higher-than-normal risk of the disease. The drug is already sold for urinary problems, and no [heart failure](#) risks have been seen with that use, doctors say.

Results of a study testing it as a cancer preventive were given at a medical conference last year, but the heart risk information was not known at that time, a Glaxo spokeswoman said. Full results are being published in Thursday's [New England Journal of Medicine](#).

The study involved 6,700 men with high scores from PSA blood tests but no sign of cancer on biopsy. They were given Avodart or dummy pills and new biopsies four years later. [Prostate cancer](#) was found in 25 percent of those on dummy pills and 20 percent of those on Avodart.

That's the same risk reduction as other studies have found from a similar drug, finasteride, sold in generic form and as Proscar, made by Merck & Co. Inc. Studies did not find an increased risk of heart failure with Proscar. In the Avodart study, heart failure developed in 30 men on the drug versus only 16 on dummy pills.

Further analysis suggests that men who developed heart failure while on Avodart also tended to be taking certain other drugs, said Glaxo spokeswoman Sarah Alspach. The higher heart failure rate in this study "is unexpected and inconsistent" with previous research, she said.

Last year, a panel of health experts recommended that men consider Proscar or Avodart if they are regularly getting screened for prostate cancer. But the Avodart study was not available when the advice was developed.

The two drugs work in different ways and may not have the same safety profile, said Dr. Barnett Kramer, a National Institutes of Health scientist who led the expert panel and had no role in the study.

In the full Avodart results, "the important detail is there's a heart failure signal here that was unanticipated," Kramer said.

Dr. Otis Brawley, who helped run the study before becoming the American Cancer Society's chief medical officer in 2007, said the heart failure risk may be a fluke, but men would need to be watched for it. If it develops, "it's reason to stop the drug," he said.

How many men would opt to take either drug for prostate cancer prevention is unclear. The cost is about \$3 a pill. To prevent a single additional case of cancer, 71 men would have to take Proscar for seven years, doctors have calculated.

Prostate cancer is the most common non-skin cancer in American men. About 192,000 new cases and 27,000 deaths from it occurred last year.

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