

FDA reviews 2 new drugs to reduce prostate cancer

November 29 2010, By MATTHEW PERRONE , AP Health Writer

(AP) -- Health regulators said Monday that two drugs from GlaxoSmithKline and Merck reduce the risk of prostate cancer in men, though scientists questioned the drugs' overall benefit, since the tumors they prevent are usually not life-threatening.

The reviewers for the Food and [Drug](#) Administration also complained that the companies only studied a small number of African Americans, who are at high risk for [prostate cancer](#).

The agency will hold a public meeting on the drugs on Wednesday.

U.K.-based [GlaxoSmithKline](#) PLC has asked the FDA to approve its drug Avodart for a new use against prostate cancer, after research showed a 23 percent reduction in low-grade prostate tumors among men taking the drug.

Merck & Co. of Whitehouse Station, N.J., achieved similar results with its drug Proscar and is asking the FDA to approve labeling about its drug's benefits in reducing prostate cancer risks. Both drugs are already approved to treat enlarged prostate.

But regulators said in an online review Monday that only a small percentage of patients studied were African Americans, who are at increased risk of the disease.

Only 4 percent of Merck's patients were African American, while

Glaxo's trial enrolled just 2 percent African American patients.

"The applicability to African-American men is not known due to marked under-representation," states the FDA's review.

FDA's review also raises broader questions about the value of preventing low-grade tumors. According to the FDA, about 80 percent of the tumors the drugs prevent are not aggressive. Because the tumors grow so slowly, they are not considered a threat to senior men with less than 20 years of life expectancy.

While the tumors may not be life threatening, Glaxo has argued that they can lead to unnecessary treatment and biopsies - a procedure where a tiny tissue sample is removed and tested for cancer. About 650,000 men had prostate biopsies last year and seventy percent of the tumors found were low-grade, according to Glaxo.

Some recent studies have suggested prostate cancer is over-diagnosed and over-treated in men - even in men with low-grade tumors. Treatment for the disease can include surgery to remove a [tumor](#), radiation therapy and chemotherapy.

On Wednesday, the FDA will ask a panel out advisers to vote on whether the safety and effectiveness of Avodart and Proscar in preventing prostate cancer. The agency is not required to follow the panel's advice, though it often does.

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