FDA OKs expanded use of prostate cancer drug

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Zytiga shows benefits for treating late-stage disease, agency says.

(HealthDay)—The approved use of the drug Zytiga has been expanded to include treatment of men with late-stage, hormone therapy-resistant prostate cancer before they undergo chemotherapy, the U.S. Food and Drug Administration announced Monday.

Zytiga was initially approved in April 2011 for treatment of prostate cancer patients whose disease had progressed after treatment with the chemotherapy drug docetaxel.

The drug decreases production of the male sex hormone testosterone. In prostate cancer, testosterone stimulates prostate tumors to grow. Drugs or surgery are used to reduce testosterone production or to block the hormone's effects.

However, some men have what's called "castration-resistant" or hormone therapy-resistant prostate cancer, which means that prostate cancer cells continue to grow even with low levels of testosterone, the FDA explained in a news release.

The expanded approval is based on a study of 1,088 men with late-stage, hormone therapy-resistant prostate cancer who took either Zytiga (abiraterone acetate) or an inactive placebo in combination with another drug called prednisone.

Median overall survival was just over 35 months for patients who took Zytiga and about 30 months for those who took the placebo, the FDA noted.

The most common side effects among patients taking Zytiga included fatigue, joint discomfort, swelling caused by fluid retention, hot flush, diarrhea, vomiting, cough, high blood pressure, shortness of breath, urinary tract infection and bruising.

This expanded approval of Zytiga was made under the FDA's priority review program, which offers an accelerated six-month review for drugs that may offer major advances in treatment or provide a treatment when no adequate therapy exists.

"Today's approval demonstrates the benefit of further evaluating a drug in an earlier disease setting and provides patients and health care providers the option of using Zytiga earlier in the course of treatment," Dr. Richard Pazdur, director of the Office of Oncology Drug Products in the FDA's Center for Drug Evaluation and Research, said in the FDA news release.

Zytiga is marketed by Pennsylvania-based Janssen Biotech Inc.

More information: The American Cancer Society has more about prostate cancer.