New Option For Late-Stage Prostate Cancer

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Zytiga approved for use prior to chemotherapy in men with castration resistant prostate cancer

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Men with castration-resistant prostate cancer have another treatment option. The U.S. Food and Drug Administration (FDA) has approved the expanded use of Zytiga (abirateroneacetate).

The drug can now be used prior to chemotherapy in men who have castration-resistant prostate cancer that has spread (metastasized). The medication works by decreasing production of the male hormone testosterone, which promotes tumor growth.

"Find out about all drugs used for your condition."

Zytiga was originally approved by the FDA in November, 2011 to treat prostate cancers that continued to progress after chemotherapy treatment using the agent docetaxel. The medication is a pill and is taken orally.

Testosterone stimulates prostate cancer to grow. So other treatments are designed to reduce production of the hormone or block its effects. Cancer cells continue to grow in castration-resistant prostate cancer, even when testosterone levels are low.

This approval – which was completed after only six months under the FDA's priority review program – was based on a study involving nearly 1,100 men with late-stage, castration-resistant prostate cancer who had not had chemotherapy.

Study members were given either Zytiga or a sugar pill (placebo) along with prednisone, a steroid medication. Researchers found that men who received Zytiga lived a median of 35.3 months compared to 30.1 months for those who received a placebo.

Men taking the medication reported these side effects – joint swelling or pain, fatigue, swelling from fluid retention, diarrhea, vomiting, high blood pressure, hot flush, shortness of breath, bruising and urinary tract infection.

Additionally, other side effects found in the laboratory included low red blood cell count, high amounts of the enzyme alkaline, which could signal other more serious medical problems. Also, high levels of fatty acids, sugar, and liver enzymes in the blood; and low levels of lymphocytes, phosphorous and potassium in the blood.

"The FDA approval today is a game changer, and there is no question that chemotherapy will be pushed further back in treatment," E. David Crawford, MD told dailyRx News. "This approval also means that more urologists will likely be involved in the treatment of these pre-chemotherapy patients. However, the role of chemotherapy will not disappear, investigations are ongoing to define who would benefit earlier, like those with rapid progressive disease," said Dr. Crawford, who is professor of surgery, urology, and radiation oncology, and head of the Section of Urologic Oncology at the University of Colorado Health Sciences Center in Denver.

"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," said Richard Pazdur, M.D., director of the Office of Oncology Drug Products in the FDA's Center for Drug Evaluation and Research.

Zytiga has a hefty price tag – about $6,100 for 120 250mg tablets. The medication is marketed by Janssen Biotech Inc.