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FDA NEWS RELEASE

For Immediate Release: Dec. 10, 2012

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FDA expands Zytiga's use for late-stage prostate cancer

Drug can now be used before treatment with chemotherapy

The U.S. Food and Drug Administration today expanded the approved use of Zytiga (abiraterone acetate) to treat men with late-stage (metastatic) castration-resistant prostate cancer prior to receiving chemotherapy.

The FDA initially approved Zytiga in April 2011 for use in patients whose prostate cancer progressed after treatment with docetaxel, a chemotherapy drug. Zytiga is a pill that decreases the production of 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 testosterone's effects. Some men have castration-resistant prostate cancer, meaning the prostate cancer cells continue to grow even with low levels of testosterone.

"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.

The FDA reviewed Zytiga's application for this new indication under the agency's priority review program. The program provides for an expedited six-month review for drugs that may offer major advances in treatment or provide a treatment when no adequate therapy exists.

Zytiga's safety and effectiveness for its expanded use were established in a clinical study of 1,088 men with late-stage, castration-resistant prostate cancer who had not previously received chemotherapy. Participants received either Zytiga or a placebo (sugar pill) in combination with prednisone.

The study was designed to measure the length of time a patient lived before death (overall survival) and the length of time a patient lived without further tumor growth as assessed by imaging studies (radiographic progression-free survival, or rPFS).

Patients who received Zytiga had a median overall survival of 35.3 months compared with 30.1 months for those receiving the placebo. Study results also showed Zytiga improved rPFS. The median rPFS was 8.3 months in the placebo group and had not yet been reached for patients treated with Zytiga at the time of analysis.

The most common side effects reported in those receiving Zytiga include fatigue, joint swelling or discomfort, swelling caused by fluid retention, hot flush, diarrhea, vomiting, cough, high blood pressure, shortness of breath, urinary tract infection, and bruising.

The most common laboratory abnormalities included low red blood cell count; high levels of the enzyme alkaline phosphatase, which can be a sign of other serious medical problems; high levels of fatty acids, sugar, and liver enzymes in the blood; and low levels of lymphocytes, phosphorous and potassium in the blood.

Zytiga is marketed by Horsham, Pa.-based Janssen Biotech Inc.

For more information:

[FDA approves Zytiga for late-stage prostate cancer \(April 2011\)](#)

[FDA: Office of Hematology and Oncology Products](#)

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This press release was updated on Dec. 10, 2012 at 2:30 p.m. to correct the date when Zytiga was originally approved to April 2011.

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