FDA NEWS RELEASE

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Media Inquiries: Erica Jefferson, 301-796-4988, **erica.jefferson@fda.hhs.gov (mailto:erica.jefferson@fda.hhs.gov)**
Consumer Inquiries: 888-INFO-FDA

FDA approves Zytiga for late-stage prostate cancer

The U.S. Food and Drug Administration today approved Zytiga (abiraterone acetate) in combination with prednisone (a steroid) to treat patients with late-stage (metastatic) castration-resistant prostate cancer who have received prior docetaxel (chemotherapy).

In prostate cancer, the male sex hormone testosterone stimulates prostate tumors to grow. Drugs or surgery are used to reduce testosterone production or to block testosterone's effects. However, sometimes prostate cancer can continue to grow even when testosterone levels are low. Men with these cancers are said to have castration-resistant prostate cancer.

Zytiga is a pill that targets a protein called cytochrome P450 17A1 (CYP17A1) which plays an important role in the production of testosterone. The drug works by decreasing the production of this hormone that would stimulate cancer cells to continue growing.

The application was reviewed under the FDA's priority review program, which 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 is being approved ahead of the product's June 20, 2011 regulatory goal date.

"Zytiga prolonged the lives of men with late-stage prostate cancer who had received prior treatments and had few available therapeutic options," said Richard Pazdur, M.D., director of the Office of Oncology Drug Products in the FDA's Center for Drug Evaluation and Research.

Zytiga's safety and effectiveness were established in a clinical study of 1,195 patients with late-stage castration-resistant prostate cancer who had received prior treatment with docetaxel chemotherapy. Patients received either Zytiga once daily in combination with prednisone two times a day or a placebo (sugar pill) twice daily in combination with prednisone.

The study was designed to measure overall survival, the length of time from when the treatment started until a patient's death. Patients who received the Zytiga and prednisone combination had a median overall survival of 14.8 months compared to 10.9 months for patients receiving the placebo and prednisone combination.

The most commonly reported side effects in patients receiving Zytiga included joint swelling or discomfort, low levels of potassium in the blood, fluid retention (usually of the legs and feet), muscle discomfort, hot flashes, diarrhea, urinary tract infection, cough, high blood pressure, heartbeat disorders, urinary frequency, increased nighttime urination, upset stomach or indigestion and upper respiratory tract infection.

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

For more information:

FDA: Office of Oncology Drug Products (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm091745.htm)

FDA: Approved Drugs: Questions and Answers (/Drugs/ResourcesForYou/Consumers/ucm054420.htm)

NCI: Prostate Cancer (http://www.cancer.gov/cancertopics/types/prostate)

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