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FDA NEWS RELEASE

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FDA Approves New Treatment for Advanced Prostate Cancer

The U.S. Food and Drug Administration today approved Jevtana (cabazitaxel), a chemotherapy drug used in combination with the steroid prednisone to treat men with prostate cancer. Jevtana is the first treatment for advanced, hormone-refractory, prostate cancer that has worsened during or after treatment with docetaxel, a commonly used drug for advanced prostate cancer.

In prostate cancer, the male sex hormone testosterone can cause prostate tumors to grow. Drugs, surgery, or other hormones are used to reduce testosterone production or to block it. Some men have hormone refractory prostate cancer, meaning the prostate cancer cells continue to grow, despite testosterone suppression. Different treatments are needed for men with this type of cancer.

Jevtana 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. Jevtana received approval ahead of the product's Sept. 30, 2010, goal date.

"Patients have few therapeutic options in this disease setting," said Richard Pazdur, M.D., director of the Office of Oncology Drug Products, part of the FDA's Center for Drug Evaluation and Research. "FDA was able to review and approve the application for Jevtana in 11 weeks, expediting the availability of this drug to men with prostate cancer."

Jevtana's safety and effectiveness was established in a single, 755-patient study. All study participants had previously received docetaxel. The study was designed to measure overall survival (the length of time before death) in men who received Jevtana in combination with prednisone compared with those who received the chemotherapy drug, mitoxantrone, in combination with prednisone. The median overall survival for patients receiving the Jevtana regimen was 15.1 months compared with 12.7 months for those who received the mitoxantrone regimen.

Side effects in those treated with Jevtana included decrease in infection-fighting white blood cells (neutropenia), anemia, decrease in the number of white blood cells (leukopenia), low level of platelets in the blood (thrombocytopenia), diarrhea, fatigue, nausea, vomiting, constipation, weakness (asthenia), and renal failure.

Prostate cancer, which usually occurs in older men, is the second most common cancer among men in the United States, behind skin cancer. In 2006, the most recent year for which numbers were available, 203,415 men developed prostate cancer and 28,372 men died from the disease, according to the Centers for Disease Control and Prevention.

Jevtana is marketed by Bridgewater, N.J.-based Sanofi-Aventis.

For more information:

- FDA: Office of Oncology Drug Products
- CDC: Informed Decision Making About Prostate Cancer
- NCI: Prostate Cancer

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