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News & Events

FDA NEWS RELEASE

FOR IMMEDIATE RELEASE
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FDA Approves New Indication for Taxotere -- Prostate Cancer

Today the Food and Drug Administration (FDA) approved Taxotere (docetaxel), injection in combination with prednisone (a steroid), for the treatment of patients with advanced metastatic prostate cancer. This is the first drug approved for hormone refractory prostate cancer that has shown a survival benefit.

"We consider this approval an important advance in the treatment of prostate cancer because it can help some patients live longer. Patients need as many effective treatment options as possible and Taxotere, in combination with prednisone, offers hope to certain patients who have not responded to other treatments," said Dr. Lester M. Crawford, Acting FDA Commissioner.

Prostate cancer is the second leading cause of cancer death in men and for those patients who have not responded to hormone therapy, Taxotere, in combination with prednisone, is a new treatment option that has now shown a survival advantage.

Taxotere works by inhibiting tubulin, a protein essential to cell division, thus preventing cancer cells from dividing and growing in number.

The safety and effectiveness of Taxotere was established in a randomized, multi-center global clinical trial with over 1,000 patients comparing chemotherapy with taxotere and prednisone to mitoxantrone and prednisone in men with metastatic, hormone-refractory prostate cancer. Taxotere, in combination with prednisone, given every three weeks showed a survival advantage of approximately 2.5 months over the control group in the trial.

The most common adverse events reported were nausea, alopecia (hair loss), and bone marrow suppression. In addition, fluid retention and peripheral neuropathy (tingling sensations in the extremities), known effects of taxotere, were also observed.

The American Cancer Society estimates there will be about 230,900 new cases of prostate cancer in the United States in 2004. About 29,900 men will die of this disease this year alone.

Taxotere is distributed by Aventis Pharmaceuticals Inc. of Bridgewater, NJ.

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