



FDA Approves Taxotere® for Early Stage Breast Cancer

Earlier use of Taxotere® shown to significantly improve disease-free survival by reducing the risk of relapse in women with node-positive breast cancer

BRIDGEWATER, NJ - August 19, 2004 -

Aventis announced today that the U.S. Food and Drug Administration (FDA) has approved Taxotere® (docetaxel) Injection Concentrate in combination with doxorubicin and cyclophosphamide (TAC regimen) for the adjuvant (post surgery) treatment of patients with operable, node-positive breast cancer. The supplemental New Drug Application (sNDA) received a Priority Review designation by the FDA, which is assigned to those applications that have the potential for providing a significant therapeutic advance. The additional indication also is under review by the European regulatory authorities.

The FDA based its decision on results from a second interim analysis from the pivotal Breast Cancer International Research Group (BCIRG) 001/TAX 316 study, which demonstrated that women with node-positive, early stage breast cancer who received a Taxotere®-based chemotherapy regimen (TAC) after surgery experienced a significant 25.7

percent reduction in their risk of relapse (or the chance of their cancer returning) as compared to women treated with another adjuvant combination regimen of 5-fluorouracil, doxorubicin, and cyclophosphamide (FAC). Notably, with nearly five-years of follow-up (55 months), the significant reduction in the risk of relapse of this Taxotere®-based regimen was observed regardless of a woman's hormone receptor status.

Additionally, at the time of this interim analysis, based on a total of 219 deaths, overall survival was longer for TAC than FAC (hazard ratio=0.69, 2-sided 95% CI=0.53, 0.90). There will be further analysis at the time survival data mature.

"The FDA approval of Taxotere® in early stage breast cancer demonstrates the continued effectiveness of this agent across various stages of breast cancer," said Frank Douglas, MD, PhD, Executive Vice President of Drug Innovation and Approval and a Member

of the Board of Management at Aventis. "More importantly, the approval of Taxotere® marks an important advance for women diagnosed with node-positive, early stage breast cancer, given the significant improvement in disease-free survival."

It is estimated that worldwide more than 300,000 women per year will be diagnosed with node-positive, early stage breast cancer. Most patients with early stage breast cancer (cancer localized to the breast with or without invasion of the lymph nodes under the arm) undergo surgery to remove the tumor. After surgery, most patients receive additional treatments, which may include chemotherapy to reduce the probability of tumor recurrence. Earlier diagnosis of breast cancer results in earlier treatment and may offer a better chance for cure.

"The nearly five-year follow-up data from the study suggest that by substituting Taxotere® for 5-fluorouracil in a standard

continued on page 25