FDA Approves Taxotere® for Women With Early-Stage Breast Cancer

(NAPSA)—There's encouraging news for the over 215,000 American women who will be diagnosed with breast cancer this year: a drug currently used to treat women with advanced breast cancer has been shown to reduce the risk of relapse for women with early-stage breast cancer.

The U.S. Food and Drug Administration has approved Taxotere® (docetaxel) Injection Concentrate in combination with two other agents, doxorubicin and cyclophosphamide, for the post-surgery treatment of women with node-positive, early-stage breast cancer. A node-positive diagnosis indicates that the cancer cells have reached the axillary (underarm) lymph nodes, and may have spread to other organs of the body as well.

Taxotere®, initially approved by the FDA for women with metastatic (advanced) breast cancer after failure of prior chemotherapy, now can be used to treat women with early-stage breast cancer. The FDA based its approval on data from a clinical study, which demonstrated that a Taxotere®-based treatment regimen had a 25.7 percent reduction in their risk of relapse (or the chance of the cancer returning).

Most patients with early-stage breast cancer initially undergo surgery like a lumpectomy and mastectomy to remove their tumor, according to the American Cancer Society (ACS). Patients are often given additional treatment, like chemotherapy, after surgery to reduce the probability of the cancer returning. The FDA approval indicates that by substituting Taxotere® in a standard chemotherapy-based regimen, patients may reduce the chance of their cancer returning.

"Our initial experience with Taxotere® has been with patients in the advanced setting, but results of the study demonstrated its effectiveness at earlier stages of the disease," said John Mackey, MD, Chairman, Northern Alberta Breast Cancer Program, Cross Cancer Institute and lead investigator in the trial. "With the FDA's approval, we now have a treatment option that may be able to help more women with early-stage breast cancer reduce the chance of the cancer returning."

According to the ACS, breast cancer is the most common cancer among women other than skin cancer. It is the second-leading cause of cancer death in women after lung cancer and is the leading cause of cancer death among women ages 20 to 59. It is estimated that one out of seven women will develop breast cancer in her lifetime.

The earlier breast cancer can be found, the better the chances that treatment will work. The ACS recommends the following for finding breast cancer early in women without symptoms: Women age 40 and older should have an annual mammogram and annual clinical breast examination; women in their 20s and 30s should have a clinical breast exam every three years; and breast self-examination is recommended for women beginning in their 20s.

Among patients receiving Taxotere® the most common severe adverse events were low blood cell count, fatigue, diarrhea, and mouth and throat irritation.

The most common non-severe side effects include hair loss, numbness, a tingling and/or burning sensation, dyspnea, rash, nail changes, nausea, vomiting, and muscle pain.

Less common severe or potentially life threatening side effects include fluid retention, infections, and allergic reactions.

Patients 65 years of age or older may experience some side effects more frequently. For more information about Taxotere®, visit www.taxotere.com or see full prescribing information including boxed WARNING. For more information about ongoing clinical trials, call 1-800-RxTrial or visit www.aventisoncology.com.