

Bridgewater, NJ – December 3, 2002 – Aventis announced today that its chemotherapeutic agent Taxotere® (docetaxel) for Injection Concentrate was approved by the United States Food and Drug Administration (FDA) as first-line therapy in patients with unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) in combination with cisplatin, who have not received prior chemotherapy. With this FDA approval, Taxotere® is the only agent indicated both for patients with newly diagnosed NSCLC, in combination with cisplatin, and for those with previously treated advanced NSCLC, as a single agent.

Lung cancer is the second most common cancer in the United States.

therapy,” said Chandra P. Belani, MD, professor of medicine at the University of Pittsburgh School of Medicine, and co-director of the Lung Cancer Program at the University of Pittsburgh Cancer Institute. “In light of low survival rates among people with this disease, this approval means more patients can hope for longer survival.”

RESULTS OF THE LARGEST RANDOMIZED PHASE III TRIAL OF NSCLC PATIENTS

The FDA approval was based on a clinical trial with 1,218 patients, comparing the effect of Taxotere® plus cisplatin or Taxotere® plus carboplatin to a standard regimen of vinorelbine plus cisplatin. Patients in

metastatic non-small cell lung cancer is another step forward in the effort to improve standards of care and treatment for those fighting this devastating disease,” said Cynthia Langhorne, director of operations at the Alliance for Lung Cancer Advocacy, Support and Education (ALCASE). “Our hope is that this new treatment option will provide physicians and their patients with an additional tool to best manage non-small cell lung cancer.”

ABOUT NON-SMALL CELL LUNG CANCER

There are two general types of lung cancer - small cell and non-small cell. Non-small cell lung cancer (NSCLC) is more common, accounting for 80

FDA APPROVES AVENTIS' TREATMENT OF PATIENTS LUNG CANCER

First Therapy Non-Small Cell

It is also the number one cause of cancer death among men and women, and has now surpassed breast cancer as the number one cancer killer of women. Lung cancer claims approximately 155,000 lives each year, accounting for 28 percent of all cancer deaths. According to the American Cancer Society, the one-year survival rate for all stages of lung cancer combined was 41 percent in 1997 and the five-year survival rate is only 15 percent.

“The approval of Taxotere® as a first-line treatment of advanced non-small cell lung cancer means that oncologists can now extend to newly diagnosed patients the benefits seen with this agent as second-line

the Taxotere plus cisplatin group had a median survival time of 10.9 months vs. 10.0 months for patients treated with vinorelbine plus cisplatin. The overall response rates were 31.6 percent for Taxotere plus cisplatin vs. 24.4 percent for vinorelbine plus cisplatin.

Additional study analysis indicated that the benefits seen in the study were maintained in patients who were 65 years of age and older. According to data from the National Cancer Institute (NCI), 68 percent of all lung cancer patients are 65 years of age and older.

“The approval of Taxotere® plus cisplatin as a first-line therapy for unresectable locally advanced or

percent of all lung cancer cases. Symptoms of NSCLC include new or persistent cough, shortness of breath, wheezing, increased sputum (sometimes containing blood), and recurrent pneumonia. Later symptoms include fatigue, decreased appetite and weight loss. If the tumor spreads to other organs, symptoms can include headaches, double vision and pain in bones, chest or abdomen.

ABOUT TAXOTERE®

Taxotere®, a drug in the taxoid class of chemotherapeutic agents, inhibits cancer cell division by essentially “freezing” the cell’s internal skeleton, which is comprised of microtubules. Microtubules assemble and