



## Press Release

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### **FDA APPROVES AVENTIS' TAXOTERE<sup>®</sup> FOR FIRST-LINE TREATMENT OF PATIENTS WITH NON-SMALL CELL LUNG CANCER**

*First Therapy Approved for Initial Treatment of  
Advanced Non-Small Cell Lung Cancer in More Than Four Years*

**Bridgewater, NJ – December 3, 2002** – Aventis announced today that its chemotherapeutic agent Taxotere<sup>®</sup> (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<sup>®</sup> 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. 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<sup>®</sup> 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 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.”

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### **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<sup>®</sup> plus cisplatin or Taxotere<sup>®</sup> plus carboplatin to a standard regimen of vinorelbine plus cisplatin. Patients in 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<sup>®</sup> plus cisplatin as a first-line therapy for unresectable locally advanced or 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 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<sup>®</sup>**

Taxotere<sup>®</sup>, 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 disassemble during a cell cycle. Taxotere<sup>®</sup> promotes their assembly and blocks their disassembly, thereby preventing cancer cells from dividing and resulting in cancer cell death.

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Taxotere<sup>®</sup> had previously been approved in the United States to treat patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy, and patients with locally advanced or metastatic NSCLC after failure of prior platinum-based chemotherapy. About one of every three patients treated for NSCLC in the United States today is treated with Taxotere-based therapy. Its most recent FDA approved indication is for its use as first-line therapy in patients with unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) in combination with cisplatin, who had not received prior chemotherapy. With this FDA approval, Taxotere<sup>®</sup> is the only agent indicated for use in both first- and second-line treatment of NSCLC. In September 2002, the Committee for Proprietary Medicinal Products (CPMP) issued a positive recommendation for Taxotere in Europe for the first-line treatment of advanced NSCLC in combination with cisplatin.

The most common severe side effects associated with Taxotere<sup>®</sup> include low white blood cell count, fatigue, fluid retention and mouth sores. The most common non-severe side effects included hair loss, neurosensory, cutaneous, nail changes, nausea and diarrhea. These side effects are generally reversible and manageable. A premedication regimen with corticosteroids is recommended in order to prevent or reduce hypersensitivity and fluid retention. Taxotere<sup>®</sup> is not appropriate therapy for patients with significant liver impairment or a low white blood cell count. Patients 65 years of age or older may experience some side effects more frequently. For more information about Taxotere, visit [www.taxotere.com](http://www.taxotere.com) or see full prescribing information including BOXED WARNINGS. For more information about ongoing clinical trials, please call 1-800-RxTrial or visit [www.aventisoncology.com](http://www.aventisoncology.com).

### **About Aventis**

Aventis is dedicated to improving life by treating and preventing human disease through the discovery and development of innovative prescription drugs for important therapeutic areas as well as human vaccines. In 2001, Aventis generated sales of € 17.7 billion (\$15.8 billion), invested € 3 billion (\$2.7 billion) in research and development and employed approximately 75,000 people in its core business. Aventis corporate headquarters is in Strasbourg, France. The company's prescription drugs business is conducted in the U.S. by Aventis Pharmaceuticals Inc., which is headquartered in Bridgewater, New Jersey. Aventis Pharmaceuticals was recently named one of the top companies to work for by *Working Mother* magazine. For more information about Aventis in the U.S., please visit: [www.aventis-us.com](http://www.aventis-us.com).

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Full prescribing information is available by visiting the Aventis Pharmaceuticals U.S. Web site at <http://www.aventis-us.com>. Also available at this U.S. Web site are copies of this release or any recent release.



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*Statements in this news release other than historical information are forward-looking statements subject to risks and uncertainties. Actual results could differ materially depending on factors such as the availability of resources, the timing and effects of regulatory actions, the strength of competition, the outcome of litigation, and the effectiveness of patent protection. Additional information regarding risks and uncertainties is set forth in the current Annual Report on Form 20-F of Aventis on file with the Securities and Exchange Commission.*

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