



IN EVERY ISSUE

Breast Cancer & Lung Cancer

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FDA Gives Avastin the Green Light

The Food and Drug Administration granted accelerated approval on February 22 for Avastin (bevacizumab) as treatment for metastatic HER2-negative breast cancer. The surprise decision came following an FDA advisory committee's close 5-4 vote in December to not recommend approval based on lack of evidence that the drug prolongs survival. Final data showing a survival benefit are needed before the FDA grants full approval.

Avastin, an antiangiogenic agent that blocks the blood vessel growth to tumor sites, delayed cancer growth—the primary goal—in phase III trials, but no evidence has yet shown a survival benefit.

The phase III studies paired Avastin with Taxol (paclitaxel) or Taxotere (docetaxel) in patients with recurrent or metastatic HER2-negative breast cancer. In the Taxol trial, the progression-free survival rate with the Avastin combination reached 11.3 months versus 5.8 months for Taxol alone. Overall survival, however, only improved from 24.8 months with Taxol to 26.5 with the addition of Avastin. An increase in severe side effects was also noted—71.1 percent in the Avastin arm compared with 51 percent in the control arm. Progression-free survival also improved in the more recent Taxotere/Avastin trial, and detailed data are expected this summer at the American Society of Clinical Oncology annual meeting.

Breast cancer is the most common type of cancer for women in the United States, and second only to lung cancer in mortality, with an estimated 40,000 deaths in 2007.

The FDA approved Avastin for colorectal cancer in 2004 and for non-small cell lung cancer in 2006. Side effects can include hypertension, diarrhea, and rarely, cardiac or neurological problems. For more on Avastin, go to www.avastin.com.

Nexavar Shows No Survival Benefit in Non-Small Cell Lung Cancer

A large phase III trial studying Nexavar (sorafenib) in non-small cell lung cancer was halted in February after an interim analysis found the drug failed to improve survival.

Early results from the ESCAPE trial, which added Nexavar to a combination of

carboplatin and Taxol (paclitaxel), showed more deaths in the Nexavar arm among patients with squamous cell carcinoma, a type of lung cancer commonly linked to smoking. The international trial had enrolled more than 900 newly diagnosed patients with non-small cell lung cancer.

Other Nexavar lung cancer trials are continuing, including one combining the drug with Gemzar (gemcitabine) and cisplatin, and several with patients whose disease progressed on other treatments.

Non-small cell lung cancer accounts for about 80 percent of all lung cancers, and is the leading cause of cancer death in the United States. In 2008, an estimated 215,000 people will be diagnosed with lung cancer and 161,000 will die of the disease. Incidence and deaths from lung cancer peaked in 1991, but since then, those figures have fallen in men and somewhat stabilized in women.

Nexavar, approved for liver and advanced kidney cancers, is also being studied in melanoma and breast cancer. Common side effects include diarrhea, rash, and fatigue.

For more information on Nexavar, visit www.nexavar.com.