

IN EVERY ISSUE

Breast Cancer & Liver Cancer

BY ELIZABETH WHITTINGTON

After Priority Review, Tykerb Approved for Breast Cancer

Women with HER2-positive breast cancer make up about a quarter of all breast cancer patients, and are at higher risk for disease progression and death than women with cancers that do not overexpress HER2. Herceptin (trastuzumab), which was approved for metastatic breast cancer in 1998, has had striking results in this population, but most advanced cases eventually become resistant to the drug.

These patients now have a backup following the Food and Drug Administration's approval of Tykerb (lapatinib) on March 13 for advanced or metastatic HER2-positive breast cancer in combination with Xeloda (capecitabine) for women whose cancer progressed on other therapies, including Herceptin. Unlike Herceptin, which targets only HER2, Tykerb inhibits both HER2 and the epidermal growth factor receptor (also known as HER1)—both of which promote cell growth.

Data from a large international phase III trial showed Tykerb plus Xeloda significantly extended the time it took for cancer to progress when compared with patients taking Xeloda alone (27.1 weeks compared with 18.6 weeks, respectively). The response rate with Tykerb was also higher at 24 percent compared with 14 percent in the Xeloda-alone arm. However, researchers noted the drug did not extend survival for patients in the trial. Some patients experienced diarrhea, vomiting and rash, but most side effects were considered mild to moderate.

Tykerb is also being examined in early-stage and inflammatory breast cancers as well as cervical and head and neck cancers. For more information on Tykerb, visit www.tykerb.com or call 866-4-TYKERB (89-5372).

Nexavar Makes Headlines in Liver Cancer

A study involving Nexavar (sorafenib) in advanced liver cancer patients was stopped ahead of schedule after the drug was shown to extend overall survival.

More than 600 patients were enrolled in the phase III trial, with patients being randomized to receive either Nexavar or placebo. Once the trial was halted, all patients were given the opportunity to continue on Nexavar. Specific data on the study will be presented at the annual meeting of the American Society of Clinical Oncology in June.

A phase II trial reported last year showed Nexavar controlled cancer growth in a third of 137 liver cancer patients, and half lived beyond nine months to surpass the current seven-month life expectancy for advanced liver cancer patients. Researchers have also found a series of genes that may make it possible to identify patients who can benefit from the drug.

Nexavar, which was approved for advanced kidney cancer in late 2005, is a pill-form tyrosine kinase inhibitor that stops blood vessels from forming to feed the tumor, a process known as angiogenesis that is a problem in a number of different cancers. Common side effects from the drug include rash, hand-foot syndrome, diarrhea and high blood pressure. The drug is also being tested in cancers of the lung, breast and colon and metastatic melanoma.

With no currently approved treatments for advanced liver cancer, researchers hope Nexavar will be the first ([see “Liver Cancer: More Cases, More Causes”](#)). Bayer and Onyx Pharmaceuticals, the makers of Nexavar, plan to file the drug for approval in advanced liver cancer later this year.

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

Satraplatin Suspends Prostate Cancer Progression

Patients with hormone-refractory prostate cancer (HRPC) whose disease does not respond to chemotherapy may soon have another treatment option. Positive results from a phase III trial of the platinum compound satraplatin confirmed the drug improves progression-free survival.

Of the 950 patients randomized to receive satraplatin plus the steroid prednisone or prednisone alone, data at six months showed 30 percent of patients taking satraplatin had not progressed compared with 17 percent of patients in the prednisone-only arm. The most common side effect seen in the satraplatin arm was decreased blood cell counts.

Known as the SPARC trial (Satraplatin and Prednisone Against Refractory Cancer), results were presented at the American Society of Clinical Oncology Prostate Cancer Symposium in February. Satraplatin works by binding to the DNA of cancer cells, inhibiting their ability to divide and multiply, thus causing cell death.

The Food and Drug Administration is currently reviewing satraplatin for approval in HRPC, and if approved, it will be the first oral platinum compound on the market.

For more on satraplatin, visit www.spectrumpharm.com/satraplatin.html