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Breaking News from ASCO

BY STAFF REPORTS

Updates from the 2007 meeting of the American Society of Clinical Oncology includes news on liver, kidney, lung, colon, pancreatic and breast cancers.

The annual meeting of the American Society of Clinical Oncology was held in Chicago in early June. The gathering attracted more than 32,000 cancer researchers, physicians, and representatives from pharmaceutical and biotechnology industries to learn the latest in cancer care, treatment, and prevention. Details can be found at www.asco.org or on ASCO's consumer website, People Living With Cancer at www.plwc.org

Nexavar Becomes First Systemic Therapy to Extend Survival in Common Type of Liver Cancer

After 30 years of research and more than 100 randomized trials, Josep Llovet, MD, says doctors now have a drug that extends survival in hepatocellular carcinoma, the most common form of liver cancer, for which no drug is currently approved. Dr. Llovet, of Mount Sinai School of Medicine in New York, expects Nexavar® (sorafenib) to become the new standard of care based on results he presented from a phase III trial, known as the SHARP trial, that randomly assigned 602 patients to receive either Nexavar or a placebo. Median survival for patients in the Nexavar group was 10.7 months compared with 7.9 months in the placebo group, and time to progression was extended from 2.8 months with placebo to 5.5 months with Nexavar. Side effects of Nexavar include diarrhea and a skin reaction on the hands and feet. About 19,000 people in the United States are diagnosed with liver cancer each year, with global estimates at close to 700,000 cases. Onyx Pharmaceuticals and Bayer, makers of Nexavar, plan to file the drug for regulatory approval in liver cancer this summer. Nexavar is currently approved to treat renal cell carcinoma. —*Melissa Weber*

Avastin Delays Progression of Advanced Kidney Cancer

For the more than 40,000 new cases expected in 2007 of renal cell carcinoma—the most common type of kidney cancer—new data show Avastin® (bevacizumab) provides a good alternative to currently approved therapies for patients with metastatic renal cell carcinoma, says the study's lead investigator Bernard Escudier, MD, of the Paris-based Institute Gustave-Roussy. The phase III AVOREN study randomly assigned 649 metastatic patients to receive interferon, an approved drug that has modest effects, with or without Avastin as first-line treatment after surgery. Avastin almost doubled time to disease progression, from 5.4 months to 10.2 months. Longer follow-up is needed to confirm a trend toward improved overall survival. Side effects of Avastin include fatigue and protein in the urine. Sutent® (sunitinib), Nexavar® (sorafenib), and most recently Torisel™ (temsirolimus) are approved for advanced renal cell carcinoma. Dr. Escudier says comparative studies are now needed to compare Avastin to these approved kidney cancer drugs. —*MW*

Radiation to the Head May Prevent Metastases in Small Cell Lung Cancer

Small cell lung cancer makes up about 20 percent of all lung cancers, and is more aggressive than non-small cell lung cancer with fewer treatment options. Most SCLC patients are diagnosed after the cancer has spread outside the lung, and commonly develop brain metastases within two years of diagnosis. With the goal of reducing the risk of brain metastases in small cell lung cancer, an international randomized study of 286 advanced SCLC patients tested the impact of prophylactic cranial irradiation (PCI) in patients who responded to chemotherapy. At one year, only 14.6 percent of patients treated with PCI had symptoms of brain metastases compared with 40.4 percent of patients in the control group. Overall survival doubled in the PCI group, with 27.1 percent of patients still alive after one year compared with 13.3 percent in patients who didn't receive PCI. Side effects of PCI include headache, nausea and vomiting, and fatigue. Additional data will be presented later this year, but researchers say PCI should become standard practice for SCLC patients with extensive disease. —*Elizabeth Whittington*

Positive Axitinib Results in Thyroid and Pancreatic Cancers

The last drug approved to treat thyroid cancer was in 1974, but doctors may now have a new drug to successfully treat the disease. Axitinib, a drug that inhibits the tumor-feeding vascular endothelial growth factor, was tested in a phase II trial of 60 patients whose tumors did not respond to conventional therapy. Data from the single-arm study showed 18 patients (30 percent) had their tumors shrink by at least 30 percent, while another 25 patients (42 percent) experienced slight tumor shrinkage or no progression of their disease. Median time to progression was 18.6 months. Side effects of axitinib include fatigue, high blood pressure, and diarrhea. More than 30,000 new cases of thyroid cancer will occur in 2007, according to the American Cancer Society, and most are cured with surgery and radioactive iodine. Adriamycin® (doxorubicin) is the only drug currently approved for metastatic thyroid cancer, but the agent is very toxic, says Ezra Cohen, MD, of the University of Chicago and the trial's lead investigator, who feels the old drug should never have been approved for thyroid cancer and doesn't prescribe it to

his patients. A phase III randomized trial comparing axitinib with placebo in Adriamycin-refractory thyroid cancer is currently ongoing. Encouraging preliminary results from a randomized phase II trial were also presented for axitinib in advanced pancreatic cancer. Median overall survival for patients receiving axitinib plus Gemzar® (gemcitabine) was 6.9 months compared with 5.6 months with Gemzar alone. Axitinib is also being tested in breast, lung, and kidney cancers. —*MW*

Two Trials Show Gains in Colon Cancer

Two phase III studies, each with different treatment regimens, showed improvements in colon cancer patients. The CRYSTAL trial, which examined adding Erbitux® (cetuximab) to the chemotherapy regimen FOLFIRI (5-fluorouracil, Camptosar® [irinotecan], and leucovorin) as initial treatment in metastatic colorectal cancer, found median progression-free survival was extended by about a month in the group receiving Erbitux compared with the chemotherapy-alone arm (8.9 months versus eight months). Erbitux also showed a better overall response rate (46.9 percent versus 38.7 percent). Side effects were similar in the two arms, but a higher risk of moderate to severe diarrhea occurred in the Erbitux arm. Final results of a different trial called MOSAIC confirmed the Eloxatin® (oxaliplatin)-based chemotherapy regimen known as FOLFOX4 had a higher survival rate (78.5 percent) after six years of follow-up compared with a similar arm receiving chemotherapy alone (75.8 percent), resulting in a statistically significant risk reduction of 15 percent. Side effects of Eloxatin include low white blood cell counts and neuropathy. —*EW*

Erbitux Improves Survival in Advanced or Recurrent Head and Neck Cancer

Patients with recurrent or metastatic squamous cell carcinoma of the head and neck usually have a poor prognosis and median survival of about seven months. A phase III study of 442 patients, known as the EXTREME trial, showed that when Erbitux® (cetuximab) was added to a chemotherapy combination in the first-line setting, median survival improved from 7.4 months to 10.1 months, an improvement of 36 percent. One-year survival also improved to 39 percent in the Erbitux arm compared with 31 percent in the chemotherapy-alone arm. Follow-up data on progression-free survival and response rates are still to come. Researchers say the Erbitux combination shows the best survival benefit in 25 years over standard platinum-based chemotherapy in this patient population. Side effects of Erbitux include rash, diarrhea, and vomiting. Erbitux is currently approved for metastatic colorectal cancer and head and neck cancer in combination with radiation therapy. —*EW*

Herceptin May Be Effective in Cases with Lower HER2 Expression

Herceptin® (trastuzumab) is standard treatment for women whose breast tumors overexpress the HER2 protein. Doctors identify these cancers by measuring the staining intensity on immunohistochemistry as 0, 1+, 2+, or 3+, with 3+ having

the highest overexpression, or by distinguishing positive or negative gene amplification with fluorescent in situ hybridization (FISH). In metastatic cancer, Herceptin is approved for IHC 3+ or FISH-positive advanced cancer, leading doctors to use the same criteria for early-stage disease. However, tissue examined from the NSABP B-31 study, which was testing the effectiveness of Herceptin after surgery, found the agent works against early-stage cancers defined as FISH-negative or that have an IHC of less than 3+. Investigators concluded less strict criteria for prescribing Herceptin may be appropriate in early-stage breast cancer than in advanced disease. These results may ultimately allow more women to receive, and thus benefit from, Herceptin. It may also expose imperfections of currently used methods for determining HER2 status. Other researchers, however, were critical of such conclusions based on the small number of tumors evaluated in the study. Further confirmation is needed before criteria changes can be used in clinical practice. —*EW*