

Novel 4-drug combination proves safe for lung cancer treatment

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The four drug-combination of carboplatin and paclitaxel, with the targeted therapies bevacizumab (Avastin) and cetuximab (Erbix), is safe and may improve survival for patients with advanced lung cancer, according to a cooperative group study led by The University of Texas M. D. Anderson Cancer Center.

Presented today on the press program of the 2008 Chicago Multidisciplinary Symposium in Thoracic Oncology, sponsored by ASTRO, ASCO, IASLC and the University of Chicago, the study is the first to investigate in lung cancer a four-drug regimen of two standard chemotherapies and targeted therapies.

The Southwest Oncology Group (SWOG) Phase II study was led by Edward S. Kim, M.D., assistant professor in M. D. Anderson's Department of Thoracic Head and Neck Medical Oncology. Until now, the SWOG standard regimen for lung cancer has been carboplatin, paclitaxel and Erbix, explained Kim; with the addition of Avastin, this study looked to increase efficacy without compromising safety.

"We could not conduct a study with four chemotherapeutic agents in patients due to toxicity concerns," said Kim, the study's principal investigator. "The rationale behind the study was the finding that Avastin enhances the efficacy of existing therapy, thereby possibly improving the carboplatin-paclitaxel-Erbix regimen."

Data in lung cancer has also suggested there's a "synergistic effect" of

pairing the epidermal growth factor (EGFR) inhibitor compounds with the vascular endothelial growth factor (VEGF) inhibitor, explained Kim.

Interestingly, explained Kim, the SWOG's study came at a crossroads for lung cancer - soon after a study was presented showing the benefits of adding Avastin to standard chemotherapy, and prior to a study showing a modest survival benefit when Erbitux is combined with chemotherapy.

Between August 2006 and September 2007, the large Phase II study enrolled 110 Stage IIIB or IV non-small cell lung cancer patients, 99 of whom were able to be evaluated. Patients received six cycles of the four-drug regimen, and as maintenance, continued receiving both Avastin and Erbitux. It's unique for a trial to feature a two-drug maintenance biologic therapy combination, explained Kim.

The study met its primary endpoint, safety, defined by frequency of pulmonary hemorrhage, or bleeding, a concern related to Avastin. There were four treatment-related deaths and two due to bleeding, which is consistent with prior Avastin studies, explained Kim. Adverse events such as low blood counts and neuropathy were reported in 40 patients, also consistent with standard chemotherapy.

Secondary endpoints included response rate, progression-free survival and overall survival. Of patients enrolled, 53 percent had shrinkage of their tumors and 24 percent had stable disease. The median progression-free survival rate was seven months and overall survival was 14 months. In contrast, previous SWOG studies showed an average progression-free survival rate of five-and-a-half months and overall survival of 12 months.

"These findings were certainly compelling, and are the best results ever for a SWOG-based study for advanced lung cancer. While early, this four-drug combination seems to show promising, yet modest

improvement in efficacy without compromising patients' safety," said Kim. "Our next priority will be to analyze the tissue from this to study to help find appropriate biomarkers for the disease to best understand who might benefit from this drug regimen."

A biomarker analysis of this study is ongoing and a randomized Phase III study is planned, with the trial scheduled to open in 2009.

Source: University of Texas M. D. Anderson Cancer Center

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