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A new, international study found that the combination of two drugs delays disease progression for patients with advanced non-small cell <u>lung cancer</u> (NSCLC). Results from the Phase III "ATLAS" trial were presented today by Dr. Vincent Miller of Memorial Sloan Kettering Cancer Center (MSKCC) at the <u>American Society of Clinical Oncology</u> Annual Meeting.

This is the first study to show the addition of erlotinib to maintenance therapy prolongs progression-free survival in patients with advanced non-small cell lung cancer.

The goal of the study was to determine whether adding erlotinib (Tarceva®), a targeted agent, to maintenance therapy with bevacizumab (Avastin®), an agent commonly used as a component of treatment for advanced NSCLC would delay disease progression. Maintenance therapy involves using one or more agents of a chemotherapy regimen, but not the entire regimen, to delay disease progression and possibly improve survival after patients have previously received stronger standard chemotherapy, which can have significant side effects.

"This is the first study to show the addition of erlotinib to maintenance therapy prolongs progression-free survival in patients with advanced non-small cell lung cancer," said Dr. Miller, a thoracic oncologist at MSKCC and one of the study's lead authors. "Knowing which patients will get the greatest benefit from this combination, based on the identification of biomarkers, will be an important next step in this research," Dr. Miller added.

In total, 768 patients were randomized to receive bevacizumab plus erlotinib or bevacizumab plus placebo after initial cytotoxic chemotherapy with bevacizumab. There was a 29 percent reduction in the risk of progression for those patients treated with erlotinib, and the median progression-free survival (the time it took for the cancer to get worse) was 4.8 months for the combination versus 3.7 months for the bevacizumab-placebo group. Because a statistically significant improvement in efficacy was found in the erlotinib group, the trial was stopped early. The combination was also found to be safe and well tolerated.

Bevacizumab and erlotinib are classified as targeted therapies — agents that block tumor growth by interfering with specific molecules critical to the survival of cancer cells. Individually, both drugs have shown promise in previous studies in the treatment of NSCLC.

According to the National Cancer Institute, in 2008 the estimated number of new lung cancer cases (non-small cell and small cell combined) was 215,000 and the number of deaths was 161,840. Non-small cell lung cancer is the most common among all lung cancers and is usually associated with a history of tobacco use.



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