

## Cancer Advances: New Studies Provide Insight Into Which Lung Cancer Patients Respond Best to Gefitinib (Iressa)

Posted online July 5, 2005 on [www.jco.org](http://www.jco.org) [1]. [Read the original Southwest Oncology Group study](#) [2] [Read the original Japanese study](#) [3] Two new studies show that patients with non-small cell lung cancer (NSCLC) who have mutations in the *EGFR* gene, or who have a greater number of copies of this gene in their cancer cells, may respond better to the drug gefitinib (Iressa) than those without these genetic traits. The results could help identify patients most likely to benefit from the drug, which prior studies have shown is only effective in a relatively small group of NSCLC patients. The studies were published in the *Journal of Clinical Oncology*. **What Is Gefitinib?** Gefitinib (Iressa) was approved by the U.S. Food and Drug Administration (FDA) in 2003 to treat advanced NSCLC in patients whose cancer had worsened despite chemotherapy. The drug, which is taken orally, targets the epidermal growth factor receptor (EGFR), which may control the growth of the tumor. However, two other recent studies showed that gefitinib failed to significantly extend survival in patients with NSCLC whose disease had worsened despite chemotherapy, prompting the FDA on June 17 to limit use of the drug to patients who are existing or previous users and to patients in clinical trials. In past studies, gefitinib did increase survival in some patients, including Asians and nonsmokers, leading researchers to believe that a patient's genetic profile might predict whether they will respond to the drug. **What Do the New Studies Show?** In the first study, researchers from the Southwest Oncology Group examined the number of *EGFR* gene copies in cancer cells in 81 patients with a form of NSCLC called bronchioloalveolar carcinoma (BAC) who had received 500 mg of gefitinib daily until their disease worsened or they could no longer tolerate the side effects. Normal, noncancerous cells have only two copies of the *EGFR* gene. Researchers found that patients receiving gefitinib who had four or more copies of the *EGFR* gene in at least 40% of their cancer cells fared better than those with less than four copies—they experienced longer survival, a longer time until their disease worsened, and a better chance that tumors would stop growing or shrink. In the second study, Japanese researchers evaluated 66 patients with NSCLC whose disease returned after surgery, finding that those with mutations in the *EGFR* gene experienced a higher response rate to gefitinib, a longer time until their disease worsened, and longer survival than patients without the mutations. This research team also found that patients with a greater number of *EGFR* copies experienced a better response to gefitinib and a longer time until their disease worsened. **What Does This Mean for Patients?** The ability to predict which patients with NSCLC are most likely to respond to gefitinib by analyzing *EGFR* mutations and copy number is intriguing and promising. However, more research—including large clinical trials—is needed before these tests can be routinely used to identify patients who would benefit from gefitinib. Patients with lung cancer should discuss treatment options with their oncologist, including the possibility of participating in clinical trials of gefitinib.

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**Links:**[1] <http://www.jco.org/>[2] <http://www.jco.org/cgi/reprint/JCO.2005.01.2823v1?ijkey=ZMugDZHiPy/IQ&keytype=ref&siteid=jco>[3] <http://www.jco.org/cgi/reprint/JCO.2005.01.0793v1?ijkey=C6Utl6t8nJ/TQ&keytype=ref&siteid=jco>