

# Gefitinib Treatment Can Delay Recurrence of Intermediate-Stage Lung Cancer

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## Key Points

- The median disease-free survival was 28.7 months for patients who received gefitinib and 18 months for those who received chemotherapy.
- There were 76 patient deaths (34.2% of all enrollees) during the trial period; 41 occurred in the gefitinib group and 35 in the chemotherapy group.
- Far fewer patients experienced severe side effects with gefitinib (12%) than with chemotherapy (48%).

The targeted therapy gefitinib (Iressa) appears more effective in preventing recurrence after lung cancer surgery than the standard of care, chemotherapy. In a phase III clinical trial, patients with epidermal growth factor receptor (*EGFR*)-positive, stage II to IIIA non–small cell lung cancer (NSCLC) who received gefitinib went about 10 months longer without recurrence than patients who received chemotherapy. The study will be presented by Wu et al at the upcoming [2017 ASCO Annual Meeting](#) in Chicago (Abstract 8500).

“Adjuvant gefitinib may ultimately be considered as an important option for stage II to IIIA lung cancer patients with an active *EGFR* mutation, and we may consider routine *EGFR* testing in this earlier stage of lung cancer,” said lead study author **Yi-Long Wu, MD**, Director of the Guangdong Lung Cancer Institute, [Guangdong General Hospital](#), Guangzhou, China. “We intend to follow these patients until we can fully measure overall survival as opposed to disease-free survival, which just measures disease recurrence.”

Due to a high chance of recurrence, the 5-year survival for patients with stage II to IIIA NSCLC is only 40%. About 25% of all patients who are diagnosed with NSCLC are eligible for surgery to remove the tumors with the hope of a cure. Among that group, about 30%, or 140,000 people worldwide, have an *EGFR* mutation in the tumor and may benefit from adjuvant treatment with *EGFR*-targeted therapy to reduce the chance of recurrence. *EGFR* mutations are more common among Asian populations than European populations.

## About the Study

**Following surgery, 222 patients who had confirmed activating *EGFR* mutations in the tumor were randomly assigned to receive gefitinib or chemotherapy (vinorelbine plus cisplatin).**

Patients received gefitinib daily for 24 months or the standard therapy regimen every 3 weeks for 4 cycles. According to the authors, chemotherapy was given for a shorter period of time because it is usually not tolerated well for longer periods of time. All patients were followed for disease relapse for about 3 years.

“Two recent targeted therapy trials of adjuvant therapy did not show benefit in NSCLC, in part because they included stages I, II, and III of the disease in their design,” said Dr. Wu. “The earlier trials only looked to see if patients showed overexpression, or overactivity, of *EGFR*, but not mutations in *EGFR*. Our trial recruited patients who had been confirmed to have activating *EGFR* mutations, so we believe these reasons account for why other trials showed no benefit of a targeted therapy, while ours did.”

Gefitinib is an *EGFR* inhibitor and is only effective in cancers with mutated and overactive *EGFR*. It was initially approved by the U.S. Food and Drug Administration in 2003 as a third-line therapy for patients with advanced NSCLC, but it is now approved as initial therapy for advanced NSCLC with an *EGFR* mutation.

### Key Findings

**The median time to recurrence (disease-free survival) was 28.7 months for patients who received gefitinib and 18 months for those who received chemotherapy.** There were 76 patient deaths (34.2% of all enrollees) during the trial period; 41 occurred in the gefitinib group and 35 in the chemotherapy group. Far fewer patients experienced severe side effects with gefitinib (12%) than with chemotherapy (48%). The most common serious side effect in the gefitinib group was elevated liver enzymes, whereas patients in the chemotherapy group had more severe quality-of-life concerns, including vomiting, nausea, low blood counts, and anemia.

### Next Steps

As the researchers have a tissue repository from the surgically removed lung tumors, they plan to perform a comprehensive biomarker analysis looking for other potential biomarkers for gefitinib response or resistance, in addition to *EGFR*. Dr. Wu stated that a fuller analysis of treatment outcomes is also planned.

### Commentary

“This study identifies a subset of patients with lung cancer who can benefit from a targeted treatment that causes far fewer side effects than chemotherapy,” said ASCO President-Elect **Bruce E. Johnson, MD, FASCO**. “It’s also clear evidence that we can use precision medicine not only in patients with advanced cancer, but also in those with earlier-stage disease.”

This study received funding from Chinese Thoracic Oncology Group (CTONG) and AstraZeneca China.

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