

Submitted by:
Vinson Lee, PharmD, Scientist
Medical Communications, Medical Affairs
Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080
Phone: (650) 225-3952
Email: vinsonl@gene.com
Date of request: June 18, 2010
NCCN Guidelines Panel: Lung Cancer

On behalf of Genentech, I respectfully request the NCCN Lung Cancer Guideline Panel to review the enclosed data for Tarceva[®] (erlotinib) monotherapy in the maintenance treatment of non-small cell lung cancer (NSCLC).

Specific Changes: Consider updating the NCCN Guidelines with the final results from the Phase III SATURN trial.¹

FDA Clearance: FDA has approved Tarceva monotherapy for the maintenance treatment of patients with locally advanced or metastatic NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. Please refer to the enclosed prescribing information for the full FDA-approved indications and safety information.

Rationale: Final results from the SATURN trial were recently published by Lancet Oncology on June 1, 2010.¹ The SATURN trial is the pivotal study supporting the FDA-approved indication of Tarceva monotherapy in the maintenance treatment of NSCLC.¹⁻³

The following enclosures are included for your review (copyright-paid where applicable):

- Cappuzzo F, Ciuleanu T, Stelmakh L, et al. Erlotinib as maintenance treatment in advanced non-small-cell lung cancer: a multicentre, randomised, placebo-controlled phase 3 study. Lancet Oncol 2010;11: 521-529.
- Tarceva Prescribing Information

Cited References

1. Cappuzzo F, Ciuleanu T, Stelmakh L, et al. Erlotinib as maintenance treatment in advanced non-small-cell lung cancer: a multicentre, randomised, placebo-controlled phase 3 study. Lancet Oncol 2010;11: 521-529.
2. Cappuzzo F, Ciuleanu T, Stelmakh L, et al. SATURN: a double-blind, randomized, phase III study of maintenance erlotinib versus placebo following non-progression with 1st-line platinum-based chemotherapy in patients with advanced NSCLC. J Clin Oncol 27:15s, 2009 (suppl; Abstract #8001).
3. Cappuzzo F, Ciuleanu T, Stelmakh L, et al. SATURN: a double-blind, randomized, phase III study of maintenance erlotinib versus placebo following non-progression with 1st-line platinum-based chemotherapy in patients with advanced NSCLC. Presented at the 2009 American Society of Clinical Oncology in Orlando, FL; May 29-June 2, 2009. ASCO Oral Presentation.
4. Tarceva[®] [package insert]. Genentech USA, Inc. and OSI Pharmaceuticals, Inc.; South San Francisco, CA. and Melville, NY.