

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
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NCCN Guidelines Panel: Lung Cancer

On behalf of Genentech, I respectfully request the NCCN Lung Cancer Guideline Panel to review the enclosed data on the addition of Tarceva[®] (erlotinib) to Avastin[®] (bevacizumab) following treatment with platinum-containing doublet chemotherapy and Avastin for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.

Specific Changes: Consider the final results from the Phase III ATLAS trial for updating the Lung Cancer Guidelines.

FDA Clearance: FDA has not approved the addition of Tarceva to Avastin following treatment with platinum-containing doublet chemotherapy and Avastin for the 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 Avastin and Tarceva for the full FDA-approved indications and safety information.

Rationale: Final results from the Phase III ATLAS trial were recently presented as an abstract and poster at the 2010 American Society of Clinical Oncology (ASCO) meeting in Chicago, IL.^{1,2} In the ATLAS trial, patients with Stage IIIB/IV non-small cell lung cancer (NSCLC) were treated with platinum-containing doublet chemotherapy and Avastin followed by Avastin with or without Tarceva until disease progression.¹⁻⁴

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

- Kabbinavar F, Miller VA, Johnson BE, et al. Overall survival in ATLAS, a phase IIIb comparing bevacizumab therapy ± erlotinib after completion of chemotherapy with bevacizumab for first-line treatment of locally advanced, recurrent, or metastatic non-small cell lung cancer (NSCLC). Presented at the 2010 American Society of Clinical Oncology in Chicago, IL; June 4- June 8, 2010. ASCO Poster #7526.
- Avastin Prescribing Information
- Tarceva Prescribing Information

Cited References

1. Kabbinavar F, Miller VA, Johnson BE, et al. Overall survival in ATLAS, a phase IIIb comparing bevacizumab therapy ± erlotinib after completion of chemotherapy with bevacizumab for first-line treatment of locally advanced, recurrent, or metastatic non-small cell lung cancer (NSCLC). J Clin Oncol 28:7s, 2010 (suppl; Abstract #7526).
2. Kabbinavar F, Miller VA, Johnson BE, et al. Overall survival in ATLAS, a phase IIIb comparing bevacizumab therapy ± erlotinib after completion of chemotherapy with bevacizumab for first-line treatment of locally advanced, recurrent, or metastatic non-small cell lung cancer (NSCLC). Presented at the 2010 American Society of Clinical Oncology in Chicago, IL; June 4- June 8, 2010. ASCO Poster #7526.

3. Miller VA, O'Connor P, Soh C-H, et al. A randomized, double blind, placebo controlled, Phase IIIb trial (ATLAS) comparing bevacizumab (B) therapy with or without erlotinib (E) after completion of chemotherapy with B for 1st-line treatment of locally-advanced, recurrent, or metastatic non-small cell lung cancer (NSCLC). *J Clin Oncol* 27:15s, 2009 (suppl; Abstract #LBA8002).
4. Miller VA, O'Connor P, Soh C-H, et al. A randomized, double blind, placebo controlled, Phase IIIb trial (ATLAS) comparing bevacizumab (B) therapy with or without erlotinib (E) after completion of chemotherapy with B for 1st-line treatment of locally-advanced, recurrent, or metastatic non-small cell lung cancer (NSCLC). Presented at the 2009 American Society of Clinical Oncology in Orlando, FL; May 29-June 2, 2009. ASCO Oral Presentation.
5. Avastin® [package insert]. Genentech USA, Inc.; South San Francisco, CA.
6. Tarceva® [package insert]. Genentech USA, Inc. and OSI Pharmaceuticals, Inc.; South San Francisco, CA. and Melville, NY.