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. 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.

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

- Avastin Prescribing Information
- Tarceva Prescribing Information

Cited References


