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NCCN Guidelines Panel: Non-Small Cell Lung Cancer Guideline Panel

On behalf of Genentech, I respectfully request the NCCN Non-Small Cell Lung (NSCLC) Cancer Guideline Panel to review the enclosed data on the use of Tarceva® (erlotinib) in advanced non-small cell lung cancer.

Specific Changes: For your consideration, data have been recently been presented on Tarceva® (erlotinib) in previously untreated advanced NSCLC patients with EGFR activating mutations.[1-4]

FDA Clearance: Results from two, multicenter, placebo-controlled, randomized, Phase III trials conducted in first-line patients with locally advanced or metastatic NSCLC showed no clinical benefit with the concurrent administration of Tarceva with platinum-based chemotherapy [carboplatin and paclitaxel or gemcitabine and cisplatin] and its use is not recommended in that setting.[5] Tarceva monotherapy is indicated for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least 1 prior chemotherapy regimen and the maintenance treatment of patients with locally advanced or metastatic NSCLC whose disease has not progressed after 4 cycles of platinum-based first-line chemotherapy. Please refer to the enclosed prescribing information for the full FDA-approved indications and safety information.

Rationale: Conducted by the Spanish Lung Cancer Group, the EURTAC trial is a prospective, Phase III, randomized study evaluating Tarceva against platinum-based chemotherapy in previously untreated advanced NSCLC patients.[1,2] The primary endpoint is progression-free survival (PFS) and secondary endpoints include response, overall survival (OS), and safety. Based on interim results, Tarceva showed statistically significant improvement in PFS compared with platinum-based chemotherapy. The most common adverse events were asthenia, anemia, nausea, and neutropenia in the chemotherapy arm and diarrhea, asthenia, and rash in the Tarceva arm.[2]

The OPTIMAL trial is a Phase III, randomized, open-label study in Asian patients comparing Tarceva with gemcitabine/carboplatin in first-line NSCLC.[3,4] The primary endpoint is PFS, while secondary endpoints include overall response rate, OS, quality of life (QOL), and safety. An updated analysis continued to show a statistically significant benefit in PFS. Patients also experienced clinically relevant improvement in QOL. No safety data were reported.

Due to copyright reasons, we are unable to provide a reprint of the abstracts at this time. Please go to www.asco.org to view the abstract.

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

- Zhou C, Wu YL, Chen G, et al. Updated efficacy and quality-of-life (QoL) analyses in OPTIMAL, a phase III, randomized, open-label study of first-line erlotinib versus gemcitabine/carboplatin in patients with EGFR-activating mutation-positive (EGFR Act Mut+) advanced non-small cell lung cancer (NSCLC). Presented at the 47th American Society of Clinical Oncology in Chicago, IL; June 3-7, 2011. ASCO Poster #7520.

- Tarceva Prescribing Information

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Cited References

1. Rosell R, Gervais R, Vergnenegre A et al. Erlotinib versus chemotherapy (CT) in advanced non-small cell lung cancer (NSCLC) patients (p) with epidermal growth factor receptor (EGFR) mutations: Interim results of the European Erlotinib Versus Chemotherapy (EURTAC) phase III randomized trial. Presented at the 47th American Society of Clinical Oncology in Chicago, IL; June 3-7, 2011. ASCO Oral Presentation.

2. Rosell R, Gervais R, Vergnenegre A et al. Erlotinib versus chemotherapy (CT) in advanced non-small cell lung cancer (NSCLC) patients (p) with epidermal growth factor receptor (EGFR) mutations: Interim results of the European Erlotinib Versus Chemotherapy (EURTAC) phase III randomized trial. J Clin Oncol 29: 2011. ASCO Abstract #7503.

3. Zhou C, Wu YL, Chen G, et al. Updated efficacy and quality-of-life (QoL) analyses in OPTIMAL, a phase III, randomized, open-label study of first-line erlotinib versus gemcitabine/carboplatin in patients with EGFR-activating mutation-positive (EGFR Act Mut+) advanced non-small cell lung cancer (NSCLC). Presented at the 47th American Society of Clinical Oncology in Chicago, IL; June 3-7, 2011. ASCO Poster #7520.

4. Zhou C, Wu YL, Chen G, et al. Updated efficacy and quality-of-life (QoL) analyses in OPTIMAL, a phase III, randomized, open-label study of first-line erlotinib versus gemcitabine/carboplatin in patients with EGFR-activating mutation-positive (EGFR Act Mut+) advanced non-small cell lung cancer (NSCLC). J Clin Oncol 29: 2011. ASCO Abstract #7520.

5. Tarceva Prescribing Information