Tarceva® (erlotinib) – Updated Indication

- On October 18, 2016, the FDA approved Tarceva (erlotinib) for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen.
    - Safety and efficacy of Tarceva have not been established in patients with NSCLC whose tumors have other EGFR mutations.
    - Tarceva is not recommended for use in combination with platinum-based chemotherapy.
- Previously, Tarceva was approved for:
    - First-line treatment of patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.
    - Maintenance treatment of patients with locally advanced or metastatic NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.
    - The treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen.
- Tarceva is also approved for use in combination with gemcitabine for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer.
- The recommended dose of Tarceva for NSCLC is 150 mg orally on an empty stomach. Treatment should continue until disease progression or unacceptable toxicity occurs.
    - The recommended dose of Tarceva for pancreatic cancer is 100 mg orally once daily in combination with gemcitabine. Consult the gemcitabine package label for recommended dose.