Tagrisso® (osimertinib) – New indication

- On December 18, 2020, the FDA announced the approval of AstraZeneca's Tagrisso (osimertinib), as adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
- Tagrisso is also approved for the:
  - First-line treatment of adult patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test
  - Treatment of adult patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA-approved test, whose disease has progressed on or after EGFR tyrosine kinase inhibitor therapy.
- In the U.S., approximately 229,000 adults will be diagnosed with lung cancer in 2020 and 76% of cases will be NSCLC. Approximately 20% of patients with NSCLC have EGFR mutations, which are mutations on a protein that causes rapid cell growth which helps cancer spread.
  - Although most patients who are diagnosed with NSCLC have unremovable tumors, 30% have resectable disease; thus, more than 10,000 patients nationwide each year may be candidates for Tagrisso as adjuvant therapy after tumor removal.
- The approval of Tagrisso for the new indication was based on the ADAURA trial, a randomized, double-blind, placebo-controlled study in 682 patients with early stage NSCLC and EGFR exon 19 deletions or exon 21 L858R mutation-positive who had undergone complete tumor removal. Patients were randomized to receive Tagrisso or placebo following recovery from surgery and standard adjuvant chemotherapy if given. The major efficacy outcome measure was disease-free survival (DFS) in patients with stage II – IIIA NSCLC. Additional efficacy outcome measures included DFS in the overall population (patients with stage IB – IIIA NSCLC), and overall survival (OS).
  - In patients with stage II – IIIA NSCLC, median DFS was not reached with patients treated with Tagrisso vs. 19.6 months with placebo (hazard ratio [HR] 0.17; 95% CI: 0.12, 0.23; $p < 0.0001$).
  - In the overall population, median DFS was not reached with patients treated with Tagrisso vs. 27.5 months with placebo (HR 0.20; 95% CI: 0.15, 0.27; $p < 0.0001$).
  - OS data were not mature at the time of the DFS analysis.
- The recommended dose of Tagrisso for adjuvant treatment is 80 mg orally once daily, with or without food, until disease recurrence, or unacceptable toxicity, or for up to 3 years.
  - Patients with resectable tumors for the adjuvant treatment of NSCLC should be selected based on the presence of EGFR exon 19 deletions or exon 21 L858R mutations in tumor specimens.
  - Information on FDA-approved tests for the detection of EGFR mutations is available at http://www.fda.gov/companiondiagnostics.
  - Refer to the Tagrisso drug label for additional dosing and administration recommendations.