Tagrisso® (osimertinib) – New Indication

- On April 18, 2017, the FDA approved Astra Zeneca's Tagrisso® (osimertinib), for the first-line 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 mutations, as detected by an FDA-approved test.

    — Tagrisso is also indicated for the treatment of 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 (TKI) therapy.

- According to the American Cancer Society lung cancer is the second most common cancer in both men and women. About 14% of all new cancers are lung cancers. Lung cancer is the leading cause of cancer death in the U.S, with an estimated 234,030 new diagnoses and 154,050 deaths for 2018.

- The new indication approval for Tagrisso was based on FLAURA, a clinical study of patients (n = 556) with EGFR exon 19 deletion or exon 21 L858R mutation-positive, metastatic NSCLC, who had not received previous systemic treatment for metastatic disease. Patients were randomized to Tagrisso, Iressa® (gefitinib), or Tarceva® (erlotinib) until disease progression or unacceptable toxicity. The efficacy outcomes were progression-free survival (PFS) and overall survival (OS).

    — The PFS was 18.9 months in the Tagrisso group vs. 10.2 months in the Iressa/Tarceva group (HR = 0.46, 95% CI: 0.37 to 0.57; p < 0.0001).
    — The objective response rate (ORR) was 80% in Tagrisso and 76% for the Iressa/Tarceva group (odds ratio = 1.27; 95% CI: 0.85 to 1.90; p = 0.24).
    — OS data were not mature at the time of the final PFS analysis.
    — The median duration of response was 17.2 months (95% CI: 13.8 to 22.0) with Tagrisso vs. 8.5 months (95% CI, 7.3 to 9.8) with Iressa/Tarceva.
    — The survival rate at 18 months was 83% (95% CI: 78 to 87) with Tagrisso and 71% (95% CI: 65 to 76) with Iressa/Tarceva (HR = 0.63; 95% CI: 0.45 to 0.88; p = 0.007).

- For both indications, the recommended dosage of Tagrisso is 80 mg once a day until disease progression or unacceptable toxicity.