Imfinzi® (durvalumab) – New indication

- On August 16, 2024, AstraZeneca announced the FDA approval of Imfinzi (durvalumab), in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by Imfinzi continued as a single agent as adjuvant treatment after surgery, for the treatment of adult patients with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.

- Imfinzi is also approved for NSCLC:

    — As a single agent, for the treatment of adult patients with unresectable stage III NSCLC whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy
    — In combination with tremelimumab-actl and platinum-based chemotherapy, for the treatment of adult patients with metastatic NSCLC with no sensitizing EGFR mutations or ALK genomic tumor aberrations.

- In addition to NSCLC, Imfinzi is approved for small cell lung cancer, biliary tract cancer, hepatocellular carcinoma, and endometrial cancer.

- The approval of Imfinzi for the new indication was based on AEGEAN, a randomized, double-blind, placebo-controlled study in 802 patients with previously untreated and resectable NSCLC. Patients were randomized to receive Imfinzi plus chemotherapy or placebo plus chemotherapy every three weeks for four cycles prior to surgery, followed by Imfinzi or placebo every four weeks (for up to 12 cycles) after surgery. The population for efficacy analyses was a modified intent-to-treat (mITT) which excluded patients with known EGFR mutations or ALK rearrangements. The major efficacy measures were pathological complete response (pCR) and event-free survival (EFS).

    — Median EFS was not reached in the Imfinzi arm vs. 25.9 months in the placebo arm (hazard ratio 0.68, 95% CI: 0.53, 0.88; 0.0039).
    — The pCR rate was 17.2% in the Imfinzi arm vs. 4.3% in the placebo arm (difference 13.0, 95% CI: 8.7, 17.6; p < 0.0001).

- The most common adverse reactions (≥ 20%) with Imfinzi use in patients with resectable, stage II/III NSCLC (neoadjuvant/adjuvant) were anemia, nausea, constipation, fatigue, musculoskeletal pain, and rash.

- The recommended dose of Imfinzi for neoadjuvant and adjuvant treatment of resectable NSCLC is:

    — Patients with a body weight of ≥ 30 kg:
        - Neoadjuvant: 1,500 mg in combination with chemotherapy every 3 weeks for up to 4 cycles prior to surgery
        - Adjuvant: 1,500 mg as a single agent every 4 weeks for up to 12 cycles after surgery.
    — Patients with a body weight of < 30 kg:
        - Neoadjuvant: 20 mg/kg every 3 weeks in combination with chemotherapy for up to 4 cycles prior to surgery
        - Adjuvant: 20 mg/kg every 4 weeks for up to 12 cycles as a single agent after surgery.

Continued . . .

    - Treatment should be continued until disease progression that precludes definitive surgery, recurrence, unacceptable toxicity, or a maximum of 12 cycles after surgery.

- Refer to the Imfinzi drug label for dosing for all its other indications.