Imfinzi® (durvalumab) – New indication

- On December 5, 2024, AstraZeneca announced the FDA approval of Imfinzi (durvalumab), as a single agent, for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (cCRT).

- Imfinzi is also approved, in combination with etoposide and either carboplatin or cisplatin, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

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

- The approval of Imfinzi for the new indication was based on ADRIATIC, a randomized, double-blind, placebo-controlled study in 530 patients with histologically or cytologically confirmed LS-SCLC whose disease had not progressed following cCRT. The major efficacy measures were overall survival (OS) and progression-free survival (PFS).

    - The median OS was 55.9 months with Imfinzi vs. 33.4 months with placebo (hazard ratio [HR] 0.73, 95% CI: 0.57, 0.93; p = 0.0104).
    - The median PFS was 16.6 months with Imfinzi vs. 9.2 months with placebo (HR 0.76, 95% CI: 0.61, 0.95; p = 0.0161).

- The recommended intravenous dose of Imfinzi for the treatment of LS-SCLC is 1,500 mg every 4 weeks for patients with a body weight of ≥ 30 kg and 20 mg/kg every 4 weeks for patients with a body weight of < 30 kg. Treatment should continue until disease progression, unacceptable toxicity, or a maximum of 24 months.

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