Imfinzi® (durvalumab) – New indication

- On March 30, 2020, AstraZeneca announced the FDA approval of Imfinzi (durvalumab), 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).

- Imfinzi is also approved for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma and adult patients with unresectable Stage III non-small cell lung cancer (NSCLC).

- Lung cancer is the leading cause of cancer death among both men and women. Lung cancer is broadly split into non-small cell lung cancer (NSCLC) and SCLC, with about 15% classified as SCLC.

    — About two thirds of SCLC patients are diagnosed with ES-SCLC, in which the cancer has spread widely through the lung or to other parts of the body.
    — Prognosis is particularly poor, with a 5-year survival of only 6% for all SCLC patients.

- The approval of Imfinzi for the new indication was based on CASPIAN, a randomized, active-controlled, open-label study in previously untreated ES-SCLC. Patients were randomized to Imfinzi plus investigator's choice of carboplatin or cisplatin plus etoposide (n = 268) vs. investigator's choice of carboplatin or cisplatin plus etoposide (n = 269). In the experimental arm, patients were treated with four cycles of chemotherapy while the control arm allowed up to six cycles of chemotherapy and optional prophylactic cranial irradiation. The major efficacy outcome measure was overall survival (OS). Additional efficacy outcome measures were progression-free survival (PFS) and objective response rate (ORR).

    — Median OS was 13.0 months (95% CI: 11.5, 14.8) for the Imfinzi plus chemotherapy arm vs. 10.3 months (95% CI: 9.3, 11.2) for the chemotherapy alone arm (hazard ratio [HR] 0.73; 95% CI: 0.59, 0.91; p =0.0047).
    — PFS (96% of total planned events) showed a HR of 0.78 (95% CI: 0.65, 0.94), with median PFS of 5.1 months (95% CI: 4.7, 6.2) in the Imfinzi plus chemotherapy arm vs. 5.4 months (95% CI: 4.8, 6.2) in the chemotherapy alone arm.
    — ORR was 68% (95% CI: 62, 73) in the Imfinzi plus chemotherapy arm and 58% (95% CI: 52, 63) in the chemotherapy alone arm.

- The most common adverse reactions (≥ 20%) with Imfinzi use in patients with ES-SCLC were nausea, fatigue/asthenia, and alopecia.

- The recommended dose of Imfinzi for the treatment of ES-SCLC is 1500 mg administered as an intravenous infusion over 60 minutes, in combination with chemotherapy every 3 weeks (21 days) for 4 cycles, followed by 1500 mg every 4 weeks as a single agent. Patients should be treated until disease progression or unacceptable toxicity

    — Refer to the Imfinzi drug label for dosing for all its other indications.
    — Refer to the etoposide and carboplatin or cisplatin drug labels for dosing recommendations.