Imfinzi® (durvalumab) plus Imjudo® (tremelimumab-actl) – New indication

- On November 11, 2022, AstraZeneca announced the FDA approval of Imfinzi (durvalumab), in combination with Imjudo (tremelimumab-actl) and platinum-based chemotherapy, for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

- Imfinzi plus Imjudo is also approved for the treatment of adult patients with unresectable hepatocellular carcinoma.

- Additionally, Imfinzi is approved:

    - 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 etoposide and either carboplatin or cisplatin, for the first-line treatment of adult patients with extensive-stage small cell lung cancer.
    - In combination with gemcitabine and cisplatin, for the treatment of adult patients with locally advanced or metastatic biliary tract cancer.

- The approval of the new indication for Imjudo and Imfinzi was based on POSEIDON, a randomized, open-label, active-controlled study in previously untreated metastatic NSCLC patients with no sensitizing EGFR mutation or ALK genomic tumor aberrations. Patients were randomized to receive Imfinzi in combination with Imjudo and platinum-based chemotherapy, Imfinzi and platinum-based chemotherapy (an unapproved regimen for metastatic NSCLC), or platinum-based chemotherapy. The major outcome measures were progression free survival (PFS) and overall survival (OS) of Imfinzi and Imjudo in combination with platinum-based chemotherapy compared to platinum-based chemotherapy alone (N = 675). Additional outcome measures were overall response rate (ORR) and duration of response (DOR).

    - Median OS was 14.0 months and 11.7 months for Imfinzi plus Imjudo and chemotherapy vs. platinum-based chemotherapy alone, respectively (hazard ratio [HR] 0.77, 95% CI: 0.65, 0.92; p = 0.00304).
    - Median PFS was 6.2 months and 4.8 months for Imfinzi plus Imjudo and chemotherapy vs. platinum-based chemotherapy alone, respectively (HR 0.72, 95% CI: 0.60, 0.86; p = 0.00031).
    - The ORR was 39% (95% CI: 34, 44) and 24% (95% CI: 20, 29) for Imfinzi plus Imjudo and chemotherapy vs. platinum-based chemotherapy alone, respectively.
    - Median DOR was 9.5 months (95% CI: 7.2, not reached) and 5.1 months (95% CI: 4.4, 6.0) for Imfinzi plus Imjudo and chemotherapy vs. platinum-based chemotherapy alone, respectively.

- The most common adverse reactions (≥ 20%) with Imfinzi plus Imjudo use were nausea, fatigue, musculoskeletal pain, decreased appetite, rash, and diarrhea.

- Refer to the Imfinzi and Imjudo drug labels for the complete recommended dosage schedule for NSCLC and their other uses.