Imfinzi® (durvalumab) – New indication

- On February 16, 2018, the FDA announced the approval of AstraZeneca's Imfinzi (durvalumab), for the treatment of patients with unresectable stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

- Imfinzi is also approved for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

- According to the National Cancer Institute, lung cancer was the leading cause of cancer death in the U.S, with an estimated 222,500 new diagnoses and 155,870 deaths in 2017. Approximately 30% of patients with NSCLC present with stage III disease.

- The new indication approval for Imfinzi was based on the PACIFIC study that enrolled 713 patients with unresectable stage III NSCLC. Patients were randomized to receive Imfinzi or placebo every 2 weeks for up to 12 months or until unacceptable toxicity or progression. The efficacy outcomes were progression-free survival (PFS) and overall survival (OS).

    — The interim PFS was 16.8 months in the Imfinzi group vs. 5.6 months in the placebo group (hazard ratio = 0.52 [95% CI: 0.42, 0.65]; $p < 0.0001$).
    — OS data were not mature at the time of the interim PFS analysis. However, AstraZeneca has agreed to a post-marketing commitment to provide this information to the FDA.
    — In addition, the overall response rate was 26% in the Imfinzi group vs. 14% in the placebo group, with 1% of patients achieving a complete response with Imfinzi vs. 0% with placebo.

- The most common adverse reactions (≥ 20%) with Imfinzi use in stage III unresectable NSCLC were cough, fatigue, pneumonitis/radiation pneumonitis, upper respiratory tract infections, dyspnea, and rash.

- The recommended dosage of Imfinzi for both indications is 10 mg/kg administered as an intravenous infusion over 60 minutes every 2 weeks.

    — For NSCLC, treatment should continue until disease progression, unacceptable toxicity, or a maximum of 12 months.
    — For urothelial carcinoma, treatment should continue until disease progression or unacceptable toxicity.