

Imfinzi® (durvalumab) – New indication

- On February 16, 2018, the <u>FDA announced</u> the approval of <u>AstraZeneca's Imfinzi (durvalumab)</u>, 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 platinumcontaining chemotherapy.
- According to the <u>National Cancer Institute</u>, 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.



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