



## Opdivo® (nivolumab) – Expanded indication

- On May 20, 2021, [Bristol Myers Squibb announced](#) the FDA approval of [Opdivo \(nivolumab\)](#), for the adjuvant treatment of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease in patients who have received neoadjuvant chemoradiotherapy (CRT).
  - Opdivo was previously approved for esophageal cancer for the treatment of patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based chemotherapy.
- Opdivo is also approved for unresectable or metastatic melanoma; adjuvant treatment of melanoma; metastatic non-small cell lung cancer; malignant pleural mesothelioma; advanced renal cell carcinoma; classical Hodgkin lymphoma; squamous cell carcinoma of the head and neck; urothelial carcinoma; microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer; hepatocellular carcinoma; and gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma.
- The approval of Opdivo for the expanded indication was based on CHECKMATE-577, a randomized, double-blind study in 794 patients with completely resected esophageal or gastroesophageal junction cancer who had residual pathologic disease following CRT. Patients were randomized to receive either Opdivo 240 mg or placebo every 2 weeks for 16 weeks followed by 480 mg or placebo every 4 weeks beginning at week 17. The primary endpoint was disease-free survival (DFS).
  - Median DFS was 22.4 months for Opdivo vs. 11.0 months for placebo (hazard ratio 0.69, 95% CI: 0.56, 0.85; p = 0.0003).
- The recommended dose of Opdivo for adjuvant treatment of resected esophageal or gastroesophageal junction cancer is 240 mg every 2 weeks or 480 mg every 4 weeks. Opdivo is administered via intravenous infusion and should be administered until disease progression or unacceptable toxicity, for a total treatment duration of 1 year.
  - Refer to the Opdivo drug label for dosing for all its other indications.



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