

Opdivo[®] (nivolumab) – New indication

- On March 4, 2022, [Bristol Myers Squibb announced](#) the FDA approval of [Opdivo \(nivolumab\)](#), in combination with platinum-doublet chemotherapy, as neoadjuvant treatment of adult patients with resectable (tumors \geq 4 cm or node positive) non-small cell lung cancer (NSCLC).
- Opdivo is also approved for unresectable or metastatic melanoma; adjuvant treatment of melanoma; metastatic NSCLC; 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; esophageal cancer; and gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma.
- The approval of Opdivo for the new indication was based on CHECKMATE-816, a randomized, open label study in 358 patients with resectable NSCLC. Patients were randomized to receive either: Opdivo and platinum-doublet chemotherapy administered intravenously every 3 weeks for up to 3 cycles, or platinum-doublet chemotherapy administered every 3 weeks for up to 3 cycles. The major efficacy outcome measure was event-free survival (EFS). Additional efficacy outcome measures included pathologic complete response (pCR) and overall survival (OS).
 - Median EFS was 31.6 months with Opdivo plus chemotherapy vs. 20.8 months with chemotherapy alone (hazard ratio [HR] 0.63, 95% CI: 0.45, 0.87; $p = 0.0052$).
 - The pCR rate was 24.0% and 2.2% with Opdivo plus chemotherapy and chemotherapy alone, respectively (estimated treatment difference 21.6, 95% CI: 15.1, 28.2; $p < 0.0001$).
 - At the time of the EFS analysis, 26% of the patients had died. A prespecified interim analysis for OS resulted in a HR of 0.57 (95% CI: 0.38, 0.87), which did not cross the boundary for statistical significance.
- The recommended dose of Opdivo for neoadjuvant treatment of NSCLC is 360 mg intravenously every 3 weeks with platinum-doublet chemotherapy on the same day every 3 weeks. The duration of therapy in combination with platinum-doublet chemotherapy is 3 cycles.
 - Refer to the Opdivo drug label for dosing for all its other indications.