



## Opdivo® (nivolumab) – Indication withdrawal

- On December 29, 2020, [Bristol Myers Squibb announced](#) that in consultation with the FDA, they have decided to [voluntarily withdraw](#) the indication for [Opdivo \(nivolumab\)](#), for the treatment of patients with metastatic small cell lung cancer (SCLC) with progression after platinum-based chemotherapy and at least one other line of therapy.
- Patients who are being treated with Opdivo for SCLC should consult with their healthcare provider in all aspects of their care.
- Opdivo was granted accelerated approval in 2018 for this indication. The accelerated approval was based on Opdivo's effect on surrogate endpoints from the Phase 1/2 CheckMate-032 trial of patients with advanced or metastatic solid tumors. However, subsequent confirmatory studies in different treatment settings, CheckMate-451 and CheckMate-331, did not meet their primary endpoints of overall survival.
- Opdivo is still approved for use 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 esophageal squamous cell carcinoma.



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