



Opdivo[®] (nivolumab) – Expanded indication

- On March 11, 2020, [Bristol-Myers Squibb](#) announced the [FDA approval](#) of [Opdivo \(nivolumab\)](#), as a single agent or in combination with [Yervoy[®] \(ipilimumab\)](#), for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with [Nexavar[®] \(sorafenib\)](#).
 - Opdivo was previously only approved for this indication as a single-agent.
 - This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.
- Opdivo is also approved for unresectable or metastatic melanoma; adjuvant treatment of melanoma; metastatic non-small cell lung cancer; small cell lung cancer; advanced renal cell carcinoma; classical Hodgkin lymphoma; squamous cell carcinoma of the head and neck; urothelial carcinoma; and microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer.
- The approval of Opdivo for the expanded indication was based on CHECKMATE-040, a multiple cohort, open-label study in patients with HCC. The efficacy of Opdivo in combination with Yervoy was evaluated in 49 patients (cohort 4). The major efficacy outcome measure was confirmed overall response rate (ORR). Duration of response (DOR) was also assessed.
 - The ORR was 33% (95% CI: 20, 48).
 - The DOR was 4.6 months to 30.5+ months.
- The recommended dose of Opdivo, when used in combination with Yervoy for the treatment of HCC, is 1 mg/kg intravenously (IV) every 3 weeks with Yervoy 3 mg/kg IV on the same day, for a total of 4 doses. After completing 4 doses of combination therapy, patients should then receive single-agent Opdivo 240 mg every 2 weeks or 480 mg every 4 weeks until disease progression or unacceptable toxicity.
 - Refer to the Opdivo drug label for dosing for all its other indications.
 - Refer to the Yervoy drug label for additional dosing recommendations.



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