



Opdivo® (nivolumab) – New indication

- On September 22, 2017, [Bristol-Myers Squibb announced](#) the FDA approval of [Opdivo \(nivolumab\)](#) injection, for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with [Nexavar® \(sorafenib\)](#).
 - This indication is approved under accelerated approval based on tumor response rate and durability 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 other oncological conditions, including melanoma, NSCLC, renal cell carcinoma, classical Hodgkin lymphoma, head and neck squamous cell cancer, urothelial carcinoma, and MSI-H or mismatch repair deficient metastatic colorectal cancer.
- HCC is the most common type of liver cancer and the fastest growing cause of cancer death in the U.S. It is estimated that there will be approximately 41,000 new cases of liver and intrahepatic bile duct cancer in 2017, with 29,000 deaths from these diseases. The majority of these cases are caused by Hepatitis B virus or Hepatitis C virus infections. However, the increasing prevalence of metabolic syndrome and nonalcoholic steatohepatitis is expected to contribute to increased rates of HCC in the U.S. in the foreseeable future.
- The approval of Opdivo for HCC was based on an open-label study involving 154 patients who progressed on or were intolerant to sorafenib. Additional eligibility criteria included histologic confirmation of HCC and Child-Pugh Class A. The primary endpoint was the overall response rate as assessed by the Response Evaluation Criteria in Solid Tumors (RECIST) and modified RECIST.
 - The overall response based on RECIST was 14.3% (95% CI: 9.2, 20.8) with 1.9% of patients achieving a complete response.
 - The overall response based on modified RECIST evaluation was 18.2% (95% CI: 12.4, 25.2).
 - The duration of response ranged from 3.2 months to 38.2+ months.
- The recommended dosage of Opdivo for HCC is 240 mg administered intravenously every 2 weeks until disease progression or unacceptable toxicity.
 - Refer to the Opdivo drug label for dosing in other FDA approved indications.



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