



## Opdivo® (nivolumab) – Indication withdrawal

- On July 23, 2021, [Bristol Myers Squibb announced](#) that the company plans to voluntarily withdraw the indication for [Opdivo \(nivolumab\)](#) as a single agent for patients with hepatocellular carcinoma (HCC) who were previously treated with [Nexavar® \(sorafenib\)](#).
  - Opdivo was first granted this indication in 2017 under the FDA's accelerated approval program.
- Bristol Myers Squibb took this action following the FDA's industry-wide evaluation of accelerated approvals for checkpoint inhibitors that have not met their post-marketing requirements demonstrating confirmatory benefit. This included a meeting of the Oncologic Drugs Advisory Committee in April and subsequent discussion with the FDA.
- Patients who are being treated with Opdivo for HCC should consult with their healthcare provider.
- Opdivo is still approved in combination with [Yervoy® \(ipilimumab\)](#), for the treatment of patients with HCC who have been previously treated with Nexavar.
- Refer to the Opdivo drug label for information regarding this indication and Opdivo's other FDA approved indications.



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