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.