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.