Opdivo® (nivolumab) – New indication

- On August 1, 2017, Bristol-Myers Squibb announced the FDA approval of Opdivo (nivolumab) for the treatment of adult and pediatric (12 years and older) patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.
    - This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR).
    - Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

- Opdivo is also approved for unresectable or metastatic melanoma, metastatic non-small cell lung cancer, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, and urothelial carcinoma.

- The new approval of Opdivo was demonstrated in the CheckMate-142 open-label study of 74 patients with locally determined dMMR or MSI-H mCRC whose disease had progressed during, after, or were intolerant to, prior treatment with fluoropyrimidine-, oxaliplatin-, or irinotecan-based chemotherapy. Efficacy outcome measures included ORR and DOR.
    - Opdivo demonstrated an ORR of 28% (95% CI: 17, 42) in patients who received prior treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.
    - The median DOR was not reached (range: 2.8+ to 22.1+ months).

- The recommended dosage of Opdivo for MSI-H or dMMR mCRC is 240 mg administered as an intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity.

- Consult Opdivo's drug label for the dosing recommendations for all other indications.