Keytruda® (pembrolizumab) – New indication

- On May 23, 2017, the FDA announced the approval of Merck's Keytruda (pembrolizumab) for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and Camptosar® (irinotecan).
    - 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.
    - The safety and effectiveness of Keytruda in pediatric patients with MSI-H central nervous system cancers have not been established.

- Keytruda is also approved to treat the following:
    - Treatment of patients with unresectable or metastatic melanoma.
    - As a single agent for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.
    - As a single agent for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS ≥ 1%) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda.
    - In combination with Alimta® (pemetrexed) and carboplatin, as first-line treatment of patients with metastatic nonsquamous NSCLC.
    - Treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma with disease progression on or after platinum-containing chemotherapy.
    - Treatment of adult and pediatric patients with refractory classical Hodgkin lymphoma, or who have relapsed after 3 or more prior lines of therapy.
    - Treatment of patients with locally advanced or metastatic urothelial carcinoma (mUC) who are not eligible for cisplatin-containing chemotherapy.
    - Treatment of patients with locally advanced or mUC who have disease progression during or following platinum-containing chemotherapy or within12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

- This is the first time the FDA has approved a cancer treatment based on a common biomarker rather than the location in the body where the tumor originated.

- MSI-H and dMMR tumors contain abnormalities that affect the proper repair of DNA inside the cell. Tumors with these biomarkers are most commonly found in colorectal, endometrial and gastrointestinal cancers, but also less commonly appear in cancers arising in the breast, prostate, bladder, thyroid gland and other places. Approximately 5% of patients with metastatic colorectal cancer have MSI-H or dMMR tumors.

- The effectiveness of Keytruda for this new indication was based on data from five open-label, single arm studies of 149 patients with MSI-H or dMMR solid tumors. Among these patients, 39.6% (95% CI: 31.7, 47.9) had a complete or partial response, and for 78% of these patients, the response lasted for ≥ 6 months.

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- The recommended dose of Keytruda in adults with MSI-H cancer is 200 mg administered as an intravenous (IV) infusion over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.

    — The recommended dose of Keytruda in children is 2 mg/kg (up to a maximum of 200 mg) administered as an IV infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity, or up to 24 months in patients without disease progression.

- Consult Keytruda's drug label for dosing recommendations in other indications.