Keytruda® (pembrolizumab) – Expanded indication

- On January 8, 2020, Merck announced the FDA approval of Keytruda (pembrolizumab), for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.

- Keytruda is also approved for other urothelial carcinoma indications, melanoma, non-small cell lung cancer, small cell lung cancer, head and neck squamous cell cancer, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, microsatellite instability-high cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, and endometrial carcinoma.

- The approval of Keytruda for the expanded indication was based on data from KEYNOTE-057, an open-label, single-arm trial in 96 patients with BCG-unresponsive, high-risk, NMIBC. Patients received Keytruda until unacceptable toxicity, persistent or recurrent high-risk NMIBC, or progressive disease. The major efficacy outcome measures were complete response and duration of response.

    — The complete response rate was 41% (95% CI: 31, 51). The duration of response was 16.2 (range: 0.0+, 30.4+).

- The recommended dose of Keytruda for the treatment of high-risk BCG-unresponsive NMIBC is 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks until persistent or recurrent high-risk NMIBC, disease progression or unacceptable toxicity, or up to 24 months in patients without disease progression.

- Refer to the Keytruda drug label for dosing for all its other indications.