OPTUMRx®

Keytruda® (pembrolizumab) – New indication

- On November 13, 2020, Merck announced the FDA approval of Keytruda (pembrolizumab), in combination with chemotherapy, for the treatment of patients with locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 (CPS ≥ 10) as determined by an FDA-approved test.
    - This indication is approved under accelerated approval based on progression-free survival (PFS). Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.
- Keytruda is also approved for 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, urothelial carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer, MSI-H or dMMR colorectal cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high cancer, and cutaneous squamous cell carcinoma.
- TNBC is an aggressive type of breast cancer that affects approximately 15 to 20% of patients with breast cancer. While some breast cancers may test positive for estrogen receptors, progesterone receptors or overexpression of human epidermal growth factor receptor 2 (HER2), TNBC tests negative for all three.
- The approval of Keytruda for the new indication was based on KEYNOTE-355, a double-blind, randomized, placebo-controlled study in 847 patients with locally recurrent unresectable or metastatic TNBC. Patients were randomized to Keytruda or placebo, plus chemotherapy. The main efficacy outcome measure was PFS. Additional efficacy outcome measures were objective response rate (ORR) and duration of response (DOR).
    - Median PFS was 9.7 months for Keytruda plus chemotherapy vs. 5.6 months with placebo plus chemotherapy (hazard ratio 0.65, 95% CI: 0.49, 0.86; p = 0.0012).
    - The ORR was 53% (95% CI: 46, 60) and 40% (95% CI: 30, 50) for Keytruda plus chemotherapy and placebo plus chemotherapy, respectively.
    - The median DOR was 19.3 months (95% CI: 9.9, 29.8) for Keytruda plus chemotherapy vs. 7.3 months (95% CI: 5.3, 15.8) for placebo plus chemotherapy.
- The recommended dose of Keytruda for the treatment of TNBC is 200 mg intravenously every 3 weeks or 400 mg every 6 weeks. Keytruda should be administered prior to chemotherapy when given on the same day. Keytruda is administered until disease progression, unacceptable toxicity, or up to 24 months.

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

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