



## Keytruda® (pembrolizumab) – Expanded indication

- On March 23, 2021, [Merck announced](#) the FDA approval of [Keytruda \(pembrolizumab\)](#), in combination with platinum- and fluoropyrimidine-based chemotherapy, for the treatment of patients with locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma that is not amenable to surgical resection or definitive chemoradiation.
  - Keytruda was previously approved for this indication as a single agent after one or more prior lines of systemic therapy for patients with tumors of squamous cell histology that express PD-L1 (CPS  $\geq$  10) as determined by an FDA-approved test.
- Keytruda is also approved for melanoma, non-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, cutaneous squamous cell carcinoma, and triple-negative breast cancer.
- The approval of Keytruda for the expanded indication was based on KEYNOTE-590, a randomized, placebo-controlled study in 749 patients with metastatic or locally advanced esophageal or GEJ carcinoma. Patients were randomized to either Keytruda or placebo and all patients received chemotherapy ([cisplatin](#) plus [fluorouracil](#)). The major efficacy endpoints were overall survival (OS) and progression-free survival (PFS). Additional efficacy endpoints were objective response rate (ORR) and duration of response (DOR).
  - Median OS was 12.4 months vs. 9.8 months for Keytruda and placebo, respectively (hazard ratio [HR] 0.73, 95% CI: 0.62, 0.86;  $p < 0.0001$ ).
  - Median PFS was 6.3 months vs. 5.8 months for Keytruda and placebo, respectively (HR 0.65, 95% CI 0.55, 0.76;  $p < 0.0001$ ).
  - The ORR was 45% and 29% for Keytruda and placebo, respectively ( $p < 0.0001$ ).
  - The median DOR was 8.3 months (range: 1.2+, 31.0+) vs. 6.0 months (range: 1.5+, 25.0+) for Keytruda and placebo, respectively.
- The recommended dose of Keytruda for the treatment of esophageal cancer 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.
  - Refer to the Keytruda drug label for dosing for all its other indications.



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