Generic Name:
Pembrolizumab
Trade Name:
Keytruda
Company:
Merck
Notes:

On July 30, FDA approved a new indication for pembrolizumab for treatment of patients with recurrent, locally advanced or metastatic, squamous cell carcinoma of the esophagus (ESCC) whose tumors express PD-L1 (Combined Positive Score [CPS] ?10), as determined by an FDA-approved test, with disease progression after one or more prior lines of systemic therapy.

FDA also approved a new use for the PD-L1 IHC 22C3 pharmDx kit as a companion diagnostic device for selecting patients for the above indication.

Efficacy was investigated in two clinical trials, KEYNOTE?181 and KEYNOTE?180. KEYNOTE-181 was a randomized, open-label, active-controlled trial that enrolled 628 patients with recurrent locally advanced or metastatic esophageal cancer who progressed on or after one prior line of systemic treatment for advanced or metastatic disease. KEYNOTE?180 was a single arm, open-label trial that enrolled 121 patients with locally advanced or metastatic esophageal cancer who progressed on or after at least two prior systemic treatments for advanced disease.

Adverse reactions in patients with esophageal cancer were similar to those in 2,799 patients with melanoma or non?small cell lung cancer treated with single-agent pembrolizumab in clinical trials. Common adverse reactions reported in at least 20% of patients receiving pembrolizumab included fatigue, musculoskeletal pain, decreased appetite, pruritus, diarrhea, nausea, rash, pyrexia, cough, dyspnea, constipation, pain, and abdominal pain.

The recommended pembrolizumab dose for esophageal cancer is 200 mg every 3 weeks.

Medication Monitor Categories:
Supplemental Approvals