

Keytruda® (pembrolizumab) - New indication

- On June 24, 2020, <u>Merck announced</u> the FDA approval of <u>Keytruda (pembrolizumab)</u>, for the treatment of patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation.
- 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 cancer, gastric cancer, esophageal
 cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma,
 endometrial carcinoma, and tumor mutational burden-high cancer.
- The approval of Keytruda for the new indication was based on KEYNOTE-629, a multi-cohort, non-randomized, open-label study. The study enrolled 105 patients with recurrent or metastatic cSCC. Patients received Keytruda every 3 weeks until documented disease progression, unacceptable toxicity, or a maximum of 24 months. The major efficacy outcome measures were objective response rate (ORR) and duration of response (DOR).
 - The ORR was 34% (95% CI: 25, 44).
 - The median DOR was not reached (range: 2.7 months, 13.1+ months).
- The recommended dose of Keytruda for the treatment of cSCC is 200 mg intravenously every 3
 weeks or 400 mg every 6 weeks. 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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