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Keytruda (pembrolizumab) Injection
Clinical Update

Clinical Update: FDA approved Keytruda (pembrolizumab) for treatment of patients with Recurrent or Metastatic Cutaneous Squamous Cell Carcinoma (cSCC) that is not curable by surgery or radiation.
FDA approval date: June 24, 2020

Keytruda is an anti-PD-1 therapy that works by increasing the ability of the body's immune system to help detect and fight tumor cells. Keytruda is a humanized monoclonal antibody that blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes which may affect both tumor cells and healthy cells. Keytruda (pembrolizumab) is indicated for the treatment of melanoma, non-small cell lung cancer, small cell lung cancer, head and neck squamous cell carcinoma, 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, tumor mutational burden-high (TMB-H) cancer, and cutaneous squamous cell carcinoma.

This approval is based on data from the Phase 2 KEYNOTE-629 trial, in which Keytruda demonstrated meaningful efficacy and durability of response, with an objective response rate (ORR) of 34% (95% CI, 25-44), including a complete response rate of 4% and a partial response rate of 31%. Among responding patients, 69% had ongoing responses of six months or longer.
The efficacy of Keytruda was investigated in patients with recurrent or metastatic cSCC enrolled in KEYNOTE-629 (NCT03284424), a multi-center, multi-cohort, non-randomized, open-label trial. The major efficacy outcome measures were ORR and DOR as assessed by blinded independent central review (BICR) according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1, modified to follow a maximum of 10 target lesions and a maximum of five target lesions per organ. Keytruda demonstrated an ORR of 34% (95% CI, 25-44) with a complete response rate of 4% and a partial response rate of 31%. Among the 36 responding patients, 69% had ongoing responses of six months or longer. After a median follow-up time of 9.5 months, the median DOR had not been reached (range, 2.7 to 13.1+ months).
Patients received Keytruda 200 mg intravenously every three weeks until documented disease progression, unacceptable toxicity or a maximum of 24 months
Patients with initial radiographic disease progression could receive additional doses of Keytruda during confirmation of progression unless disease progression was symptomatic, rapidly progressive, required urgent intervention, or occurred with a decline in performance status. Assessment of tumor status was performed every six weeks during the first year and every nine weeks during the second year.
Among the 105 patients with cSCC enrolled in KEYNOTE-629, the median duration of exposure to Keytruda was 5.8 months (range, 1 day to 16.1 months). Patients with autoimmune disease or a medical condition that required systemic corticosteroids or other immunosuppressive medications were ineligible. Adverse reactions occurring in patients with cSCC were similar to those occurring in 2,799 patients with melanoma or non-small cell lung cancer (NSCLC) treated with Keytruda as a single agent. Laboratory abnormalities (Grades 3-4) that occurred at a higher incidence included lymphopenia (11%).