

FDA OKs pembrolizumab for treatment of HNSCC

October 2019—The Food and Drug Administration approved pembrolizumab (Keytruda, Merck) for the first-line treatment of patients with metastatic or unresectable recurrent head and neck squamous cell carcinoma.

Pembrolizumab was approved for use in combination with platinum and fluorouracil for all patients and as a single agent for patients whose tumors express PD-L1 (combined positive score, ≥ 1) as determined by an FDA-approved test. The FDA also expanded the intended use for the PD-L1 IHC 22C3 pharmDx kit to include use as a companion diagnostic device for selecting patients with HNSCC for treatment with pembrolizumab as a single agent. Approval was based on KEYNOTE-048, a randomized, multicenter, three-arm, open-label, active-controlled trial conducted in 882 patients with metastatic HNSCC who had not previously received systemic therapy for metastatic disease or with recurrent disease who were considered incurable by local therapies.

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