NCCN Guidelines Panel: Head and Neck Cancers

On behalf of Merck & Co., Inc., I respectfully request the NCCN Head and Neck Cancers Panel to review the enclosed information for KEYTRUDA (pembrolizumab), in reference to NCCN Guidelines V1.2016 for Head and Neck Cancers.

Specific changes requested:

We respectfully request that KEYTRUDA (pembrolizumab) be added as an anti-PD-1 immunotherapy for patients with recurrent or metastatic head and neck squamous cell carcinoma in the NCCN guidelines for Head and Neck Cancers, including sections ADV-1 to ADV-4 (pages 64-67) and CHEM-A (pages 99-100).

FDA approval:

On August 5, 2016, FDA approved KEYTRUDA for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma with disease progression on or after platinum-containing chemotherapy. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.¹

Rationale:

This publication reports results from the expansion cohort of a phase 1b study (NCT01848834) in which patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC), irrespective of programmed death-ligand 1 (PD-L1) or human papillomavirus (HPV) status, received pembrolizumab fixed-dose 200 mg intravenously once every 3 weeks. Treatment response was assessed every 8 weeks by using computed tomography or magnetic resonance imaging. Treatment-related adverse events (AE) of any grade occurred in 62% (n=82/132) of patients, including fatigue (21%), hypothyroidism (11%), and decreased appetite (7%). Twelve patients (9%) experienced a grade 3 or 4 treatment-related AE, most commonly decreased appetite, facial swelling, and pneumonitis. Eight patients (6%) discontinued treatment due to treatment-related AEs. Overall response rate was 18% (95% CI, 12 to 26) by central imaging vendor and 20% (95% CI, 13 to 28) by investigator review. Median duration of response was not reached (range, ≥2 to ≥11 months). Six-month progression-free survival and overall survival rates were 23% and 59%, respectively. Fixed-dose pembrolizumab was well tolerated and provided a clinically meaningful overall response rate with evidence of durable responses.²

The following resources are submitted to assist the committee with their review:

1. KEYTRUDA (pembrolizumab) prescribing information. Merck & Co., Inc.

2. Chow LM et al. Antitumor Activity of Pembrolizumab in Biomarker-Unselected Patients With Recurrent and/or Metastatic Head and Neck Squamous Cell Carcinoma: Results From the Phase Ib KEYNOTE-012
Thank you for considering this request. Below is my contact information should you need to contact me for additional information.

Sincerely,

Maria Rivas, SVP
Merck & Co., Inc.
CRB-210
600 Corporate Drive
Lebanon, NJ 08833
908-236-1120 maria.rivas1@merck.com