

Meeting Library | Antitumor Activity of the Anti-PD-1 Antibody Pembrolizumab in Biomarker-Unselected Patients with R/M Head and Neck Cancer: Preliminary Results from KEYNOTE-012 Expansion Cohort

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Abstract Video Slides

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Abstract Disclosures

Background:
Pembrolizumab (MK-3475) is a humanized monoclonal antibody that blocks interaction of PD-1 with its ligands, PD-L1 and PD-L2, thereby promoting activity of tumor-specific effector T cells. KEYNOTE 012 (NCT01848834) had previously demonstrated clinical activity of pembrolizumab 10 mg/kg every 2 weeks in patients (pts) with recurrent/metastatic SCCHN enriched for PD-L1-positive tumors with a response rate of 20%. We now report on the larger SCCHN expansion cohort of KEYNOTE 012, irrespective of biomarker status using a 3-weekly fixed dose.

Methods:
Pts with advanced SCCHN irrespective of PD-L1 expression or HPV status received a fixed dose of 200 mg pembrolizumab, intravenously, every 3 weeks. Pts were evaluated every 8 weeks with radiographic imaging. The primary end point was overall response rate (ORR) per investigator assessment (RECIST 1.1). Secondary objectives included progression-free survival (PFS) and overall survival (OS). Adverse events (AEs) were assessed according to CTCAE v4. PD-L1 was assessed retrospectively by immunohistochemistry.

Results:
132 pts with recurrent/metastatic SCCHN were enrolled. Mean (SD) age was 58.9 (9.7) years; 83.3% were male; 56.8% had ≥ 2 lines of therapy for recurrent disease. 73/132 pts (55.3%) remain on treatment. Out of 132 treated pts, 99 pts were available for this preliminary efficacy analysis with a post-baseline scan or discontinued therapy prior to the scan due to clinical progression or AE. ORR (confirmed and unconfirmed) per RECIST 1.1 was 18.2% (95% CI, 11.1-27.2) with 18 partial responses and 31.3% with stable disease. Biomarker analysis is ongoing and results will be presented. Drug-related AEs of any grade occurred in 47% of all enrolled pts, and drug-related grade ≥ 3 AEs occurred in 7.6%. The most common drug-related AEs ($\geq 5\%$) of any grade were fatigue (12.1%), decreased appetite (6.8%), pyrexia (6.1%), and rash (5.3%).

Conclusions:
Pembrolizumab given at a fixed dose of 200 mg every 3 weeks was well tolerated and demonstrated a clinically meaningful ORR of 18.2% in pts with recurrent/metastatic SCCHN. Clinical trial information: NCT01848834

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