1048PD RetroSpective cohort stUdy of PD-L1 expression in REcurrent and/or MEtastatic squamous cell carcinoma of the head and neck (SUPREME-HN)

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Background: Clinically meaningful antitumour activity and improved overall survival (OS) in recurrent and/or metastatic (R/M) head and neck squamous cell carcinoma (HNSCC) have been achieved by targeting the PD-1/PD-L1 axis. Tumoral PD-L1 expression correlates with response to blocking PD-1/PD-L1 antibodies. In a retrospective study, we investigated tumoral PD-L1 expression as a prognostic biomarker in R/M HNSCC patients (pts) treated with standard of care (SOC) therapy.

Methods: Archival tumor samples from R/M HNSCC pts diagnosed between March 2011 and June 2015 at 19 institutions in 7 countries were evaluated for PD-L1 expression using the validated Ventana SP263 assay and scored as PD-L1 high ($\geq$25% of tumor cells [TC]) or low/negative (<25% of TC). Clinical-demographic data, including treatment patterns and outcomes, were extracted from medical records. Descriptive analyses were conducted and survival estimated by the Kaplan-Meier method. Progression-free survival (PFS) was defined from start of first- (1L) or second-line (2L) therapy to time of progression (on/after therapy) or death due to any cause. OS was defined from diagnosis index date of R/M disease to time of death. The Cox proportional hazards model was applied.

Results: The final dataset included 412 pts. Median age was 62.0 years (range 28.0–93.0); 79.9% were male and 88.2% white. PD-L1 expression was high in 132 (32.0%), low/negative in 264 (64.1%), unknown in 16 (3.9%). Median OS (8.2 vs 10.1 months; $P = 0.55$) and PFS from the start of 1L chemotherapy (4.2 vs 4.8 months; $P = 0.37$) did not significantly differ between PD-L1 high and low/negative pts, respectively. Median PFS following 2L chemotherapy was statistically significantly longer in PD-L1 high versus low/negative pts (4.1 vs 2.2 months; $P = 0.04$). PD-L1 status was not statistically significant in multivariate analyses of OS ($P = 0.74$) or PFS following 1L chemotherapy ($P = 0.63$); however, there was a trend for improved PFS following 2L chemotherapy ($P = 0.09$).

Conclusions: Tumoral PD-L1 expression was not significantly associated with OS or PFS following 1L SOC chemotherapy; however, it was associated with prolonged PFS following 2L SOC chemotherapy.

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