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Health-related quality of life (HRQoL) for pembrolizumab or placebo plus carboplatin and paclitaxel or nab-paclitaxel in patients with metastatic squamous NSCLC: Data from KEYNOTE-407

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Background: In the randomized, double-blind, phase 3 KEYNOTE-407 study, pembrolizumab (pembro) plus carboplatin and paclitaxel or nab-paclitaxel improved OS, PFS, and ORR and had a manageable safety profile compared with placebo (pbo) plus carboplatin and paclitaxel or nab-paclitaxel as first-line therapy for patients with metastatic squamous NSCLC. Patient-reported outcomes (PROs) were a prespecified exploratory endpoint of KEYNOTE-407 (NCT02775435).

Methods: 559 patients with previously untreated stage IV squamous NSCLC, ECOG PS 0–1, and measurable disease per RECIST v1.1 were randomized 1:1 to receive 4 cycles of pembro 200 mg Q3W or pbo Q3W plus carboplatin AUC 6 and paclitaxel 200 mg/  $\rm m^2$  Q3W or nab-paclitaxel 100 mg/m $^2$  QW, followed by pembro or pbo monotherapy for up to 35 cycles total. The EORTC QLQ-C30 and QLQ-LC13 were administered at cycles 1–7, then every 3 cycles up to week 48. Prespecified key PROs were change from baseline to weeks 9 and 18 in the QLQ-C30 global health status (GHS)/quality of life (QoL) score and time to 10-point deterioration in the composite endpoint of cough, chest pain, or dyspnea. P values are 2-sided and nominal.

Results: PRO analyses included 554 and 553 patients who completed  $\geq 1$  QLQ-C30 or  $\geq 1$  QLQ-LC13 assessment, respectively, and received  $\geq 1$  administration of study treatment. Compliance rates were similar between the groups and instruments (baseline,  $\sim 93\%-94\%$ ; week 9,  $\sim 84\%$ ; week 18,  $\sim 87\%$ ). Mean QLQ-C30 GHS/QoL baseline scores were 63.9 in the pembro combination group and 62.7 in the pbo combination group. At weeks 9 and 18, the mean score for QLQ-C30 GHS/QoL improved from baseline in the pembro combination group and decreased in the pbo combination group (least squares mean difference between groups: week 9, 3.6 points [95% CI, 0.3–6.9], P=0.0337; week 18, 4.9 points [95% CI, 1.4–8.3], P=0.0060). Median time to deterioration in the composite endpoint of cough, chest pain, or dyspnea was not reached in either group (HR, 0.79 [95% CI, 0.58–1.06]; P=0.125).

Conclusions: Addition of pembro to chemotherapy maintained or improved HRQoL measurements over chemotherapy alone, supporting its use as first-line therapy for metastatic squamous NSCLC.

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