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Neoadjuvant-adjuvant (neoadj-adj) pembrolizumab (pembro) plus standard-of-care (SOC) in resectable locally advanced head and neck squamous cell carcinoma (LA HNSCC): Participant-reported outcomes (PRO) in KEYNOTE-689

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Background

The phase 3 KEYNOTE-689 study (NCT03765918) met its primary endpoint of event-free survival with neoadj-adj pembro + SOC vs SOC in resectable LA HNSCC. We present PRO results from KEYNOTE-689.

Methods

Adults with LA HNSCC were randomized to 2 neoadj + 15 adj cycles pembro + SOC vs SOC (surgery + postoperative RT ± concomitant cisplatin). Analysis time points for EORTC QLQ-C30 and QLQ-H&N35 were wk 4 and wk 6 from neoadj pembro start (pembro arm only), and wk 25 and wk 51 from adj therapy start. Least square mean (LSM) change in global health status/quality of life (GHS/QOL), physical functioning (PF), swallowing, speech, and pain scores was a secondary endpoint of the trial. Data cutoff date was 25 July 2024; median follow-up was 38.3 (9.0–66.5) mo for all pts. PROs were evaluated in all randomized pts with ≥1 dose study treatment (including surgery only) and ≥1 PRO assessment.

Results

The PRO analysis population was 356 (pembro + SOC) and 306 (SOC) pts. Among pts expected to complete the QLQ-C30 and QLQ-H&N35 assessments at each time point, >95% completed them at baseline, >93% at wk 4 and 6, >81% at wk 25, and >88% at wk 51. In the pembro arm, LSM change from baseline (95% CI) in GHS/QOL, PF, swallowing, speech, and pain was 2.35 (0.20–4.50), –2.09 (–3.49––0.69), –3.36 (–5.90––0.83), –2.31 (–4.74–0.12), and –2.80 (–5.14––0.46) to wk 4 and –0.97 (–3.19–1.26), –3.34 (–4.92––1.76), –2.39 (–4.78––0.01), –0.74 (–3.14–1.67), and –6.27 (–8.68––3.87) to wk 6. Table shows difference (95% CI) in LSM change from baseline to wk 25 and 51 between arms. CIs overlapped between arms at all measured timepoints for all scales.

Conclusions

Health-related QOL and HNSCC symptom scores remained generally stable during the neoadj pembro phase vs baseline. Score changes from baseline were generally similar between arms in the longterm post adj RT ± cisplatin phase. Table: 1330MO

	Difference (95% CI) in LSM change from baseline to wk 25 and 51 between pembro + SOC and SOC	
	Wk 25	Wk 51
QLQ-C30 GHS/QOL	–1.29 (–4.78–2.20)	0.39 (–3.35–4.13)
QLQ-C30 PF	0.34 (–2.76–3.45)	–1.45 (–4.73–1.83)

	Difference (95% CI) in LSM change from baseline to wk 25 and 51 between pembro + SOC and SOC	
	Wk 25	Wk 51
QLQ-H&N35 swallowing	−3.28 (−8.05–1.48)	−0.48 (−5.41–4.45)
QLQ-H&N35 speech	1.30 (−3.25–5.85)	−0.24 (−5.30–4.82)
QLQ-H&N35 pain	−2.75 (−6.65–1.14)	−2.77 (−6.62–1.08)

Clinical trial identification

KEYNOTE-689 study (NCT03765918).

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Legal entity responsible for the study

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Disclosure

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